Mindfulness training for medical and psychology students

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Dissertation for the degree of Philosophiae Doctor (PhD)

Institute of Health and Society

Faculty of Medicine, University of Oslo

Dissertation date: 2014

Series of dissertations submitted to the
Faculty of Medicine, University of Oslo
No. 1820

ISBN 978-82-8264-861-5

Cover: Inger Sandved Anfinsen.
Printed in Norway: AIT Oslo AS.

Produced in co-operation with Akademika Publishing.
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Summary

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Abstract

Medical and clinical psychology students strive to be good professionals. In addition to acquiring academic knowledge and skills, they also need to build affective and inter-personal capacities. Doing so will help them to secure both their own health and well-being, and to improve their ability to help the patients they serve. Systematic reviews have shown, however, that a large proportion of such students suffer from mental distress and low quality of life: burnout increases towards the latter part of their studies and persists in their professional careers. Finding ways to promote student well-being and strengthen their coping abilities is therefore of increasing interest and importance.

Mindfulness training has been identified as a potentially valuable intervention for students. This thesis explores the evidence base for one method of mindfulness training for students, known as Mindfulness-Based Stress Reduction (MBSR), and analyses the results of a two-centre RCT conducted at the Universities of Oslo and Tromsø, Norway.

The first paper is a general review and meta-analysis of the effects of MBSR training programmes for adults. The review shows that MBSR training has a moderate and consistent effect on a number of measures of mental health for a wide range of target groups. The effects observed were similar in clinical and non-clinical populations, including students.

The second paper presents the pre- to post-intervention results of an MBSR RCT conducted in Norway, with a sample of 288 medical and psychology students. The trial showed that the intervention had a moderate effect on mental distress, and a small effect on both subjective well-being and the mindfulness facet 'non-react', compared to the control group. Only female students showed significant effects; they also reported reduced study stress and an increase in the mindfulness facet 'non-judge'.

The third paper explores the issue of which students benefited most from the MBSR programme. Our analysis shows that the personality factors of neuroticism and conscientiousness interacted with the effects of the MBSR intervention on mental distress, subjective well-being, and study stress. Increased effects were noted among students with higher stress vulnerability.

This thesis reports on additional study results related to empathy and coping. An increase in the coping style of problem solving was observed following the training.

Together, these results indicate that mindfulness training is a feasible way to decrease levels of mental distress among students and improve their well-being. Mental distress is prevalent in student populations, and we therefore recommend further intervention trials of this kind in higher education settings.

Preface

Ever since I was young, I knew I wanted to become a helper. I realised that my motivation lay in my wish to be able to come to terms with my own life. Like many people, I struggled with existential questions about the meaning of life, and suffered then from what I recognise now as a form of existential angst. In high school, after reading a book by an Indian yogi, I began yoga and meditation to help me in my own process of self-development.

My career began as an orderly in a mental hospital for a year, and it was at that stage I resolved to study medicine. While at university, I discovered that I was not the only student struggling with anxiety: several fellow students collapsed under the strains and uncertainties that student life entails.

After four years working as a hospital doctor, my career path moved towards family medicine. It soon became clear to me that many patients were coming to me with conditions that I had not been taught how to manage. Many of their problems were not simply biological ones that could be analysed, diagnosed, treated and cured. Patients presented largely with worries and everyday life problems that my biologically-based deductive medical methods were unable to heal.

By this time, my yoga and meditation practice had opened up new ways for me to meet my own personal challenges. I began to wonder if the

benefits I had experienced might be of interest to my patients, too, and so I started to teach them simple tools that would enable them to meet their life challenges in different ways. Unsurprisingly, they responded positively. Over time, I organised training groups for patients who wanted to learn about stress management. Searching the internet for others who were also interested in this topic, I came across The Stress Reduction Clinic, based at the Medical School at the University of Massachusetts where, since 1979, research has been conducted on using mindfulness training for patients. A grant from the Norwegian Medical Association (NMA) enabled me to spend three months as an intern at the Clinic.

When I returned, I was fortunate enough to receive a quality improvement grant from the NMA. I translated, adapted and tested the eight-week programme MBSR programme from Massachusetts using a wait-list randomised control trial (RCT). One hundred and forty-four patients from general practice who were suffering from stress and chronic illness participated. The study was awarded the quality prize for primary health by the NMA in 2006.

I had, by that time, started to work part-time on issues related to quality improvements in healthcare services, and began to consider how mindfulness training could improve the quality of care health professionals deliver. Moving to full-time employment at the Norwegian Knowledge Centre for the Health Services in 2007 gave me the opportunity to use part of my

time to teach mindfulness and to research the effects of mindfulness training on health professionals. This thesis presents the result of this work.

Acknowledgements

The NMA funded this thesis. After the grant was awarded, I happened to meet the Chairperson of the NMA Grant Committee and was told that members of the Committee had expressed doubts about my research when discussing the funding application. Despite this, the NMA decided that they were interested to know if the effects of mindfulness interventions could improve the health and stress-management of future doctors. For their commitment and interest in this work, I am truly grateful. In addition, I would like to express my sincere thanks to the Knowledge Centre and especially to Anders Vege and Anne Karin Lindahl, who supported me throughout this research and allowed me to commit time to this project. I would also like to thank Oluf Jensen, the main IT technician at the Knowledge Centre for invaluable help in setting up the database and randomisation procedure and for his assistance to the students when they had problems answering the protocols. His patience and perseverance is outstanding.

I would also like to thank my principal mentor, Professor Arild Bjørndal, whom I met for the first time at a social event at the Knowledge Centre in 2008. When I mentioned that I wanted to study the integration of mindfulness training into the education of health professionals, his support was immediate. Arild worked with me in developing the project that this

thesis is based on, and I am grateful for his inspiration and participation. He deserves special credit, too, for insisting that I conduct a meta-analysis of studies into the mindfulness method we wanted to test. Rightly, he said that we should not begin the study without first analysing the evidence base for this intervention. Through our work together, Arild has also become a good and highly valued friend.

I am also very grateful to my second mentor, Professor Reidar Tyssen, from the Faculty of Medicine at the University of Oslo. His support in the design of the intervention study and in the analyses of the results has been invaluable. Generously, he offered me the resources of his research unit and gave me feedback on my work. His comments helped greatly to improve the quality of this thesis.

In addition, I had the privilege of working with a research group at the University of Tromsø, which took responsibility for the delivery of the Tromsø section of the intervention study. The group included Professor Jan Rosenvinge, Professor Tore Sørli, Assistant Professor Oddgeir Friborg and Ida Solhaug, a doctoral candidate who was the project manager in Tromsø. I enjoyed close cooperation with Ida and her team throughout the process of publishing Papers II and III. In addition, I worked closely with Even Halland, a psychology student who participated both as an instructor in the courses and in the research process. Mr Halland wrote his final degree thesis on the coping dimension of the intervention study.

A heart-felt thanks to all the students who willingly and enthusiastically took part in the intervention study. I am grateful for learning so much from them.

Finally, I am deeply indebted to my wife, Ellen, who spurred me on, particularly through the times when the research process seemed to grind almost to a halt. Thank you for your loving support.

Abbreviatons

BCI	=	Basic Character Inventory
FFMQ	=	Five Facet Mindfulness Questionnaire
GHQ	=	General Health Questionnaire
JSE-HP	=	Jefferson Empathy Scale – Health Personnel
KMO	=	Kaiser-Meyer-Oklin test
MBI-S	=	Maslach Burnout Inventory - Student Version
MBSR	=	Mindfulness-Based Stress Reduction
NMA	=	Norwegian Medical Association
PCA	=	Principal Component Analysis
PMSS	=	Perceived Medical School Stress
RCT	=	Randomised Control Trial
SCL	=	Hopkins Symptom Checklist
SD	=	Standard Deviation
SWB	=	Subjective Well-being
WCCL	=	Ways of Coping Checklist

List of papers

Paper I: Michael de Vibe, Arild Bjørndal, Elizabeth Tipton, Karianne Hammerstrøm, Kristina Kowalski.

Mindfulness based stress reduction (MBSR) for improving health, quality of life, and social functioning in adults.

Campbell Systematic Review 2012, 3.

http://campbellcollaboration.org/lib/project/117/

Paper II: Michael de Vibe, Ida Solhaug, Reidar Tyssen, Oddgeir Friborg, Jan H. Rosenvinge, Tore Sørlie, Arild Bjørndal.

Mindfulness Training for Stress Management: A Randomised Controlled Study of Medical and Psychology Students.

BMC Medical Education; 13: 107.

http://www.biomedcentral.com/1472-6920/13/107

Paper III: Michael de Vibe, Ida Solhaug, Reidar Tyssen, Oddgeir Friborg, Jan H. Rosenvinge, Tore Sørlie, Even Halland, Arild Bjørndal.

Does personality moderate the effects of mindfulness training for medical and psychology students?

Mindfulness. October 2013.
http://link.springer.com/article/10.1007%2Fs12671-013-0258-y

Introduction

This thesis examines the effects of a mindfulness-based stress management programme (MBSR) on first year medical students and first and second year psychology students at the Universities of Oslo and Tromsø, Norway. It also examines the evidence base for this intervention by reviewing data from randomised controlled studies.

Background

Optimal patient care is dependent on healthcare workers being healthy and being able to cope with the strains of their roles as helping professionals. Healthcare workers must also develop the ability to be present and empathetic so that they are able to understand and communicate well with their patients. Such skills form the basis of successful therapeutic relationships. Laying the foundations for healthy and well-functioning healthcare workers is clearly vital during the period in which students are being trained. But systematic reviews have documented high levels of mental distress and low levels of life satisfaction among students in healthcare professions (1-3), and have highlighted the need for teaching relevant coping skills (4).

Why promote health and personal development among students?

Health and personal development need to be emphasised during student training. The first key reason for doing so is reduce the suffering experienced by many students during their study years.

Research conducted twenty years ago showed that approximately one third of medical students reported symptoms of anxiety, a level above the median of a normative population of psychiatric outpatients (5). More recently, a large study from the United Kingdom, with a sample size of 16,460 undergraduate students from across many different faculties, found that levels of depression among students increased steadily over time; at no time did the psychological distress that was measured return to pre-admission levels (6). A longitudinal study of Norwegian medical students (7), found that life satisfaction declined from the first to the third year of the curriculum. In another Norwegian study of medical students, one third of the 420 students who were followed from 1993 to 1999, reported mental health problems and treatment needs during their first three undergraduate years (8). Other studies have shown similarly high levels of emotional disturbance among psychology students (9, 10). In one study of 287 American clinical psychology students, for example, psychological distress, as measured by the General Health Questionnaire, was found in approximately 59% of the students (9). Similarly, a study of 292 Canadian graduate psychology

students reported clinically significant symptoms of depression in 33% of participants (11). A meta-analysis concluded that 50% of the 1,453 student participants – collectively representing a range of different study areas and nationalities – experienced significant levels of stress in the form of anxiety and/or depression (12). Some studies have also indicated that levels of stress and depression among medical students exceed those of other students (13-15), although not all studies support this conclusion (16).

Individual factors, such as previously existing psychological problems, different personality and coping styles, and contextual factors such as negative life events, levels of social support, and study stress can also contribute to deterioration in mental health (8, 9, 17, 18). Students with stress and mental health problems have reported poorer relationship quality, lower grades, and lower graduation rates than students who have not suffered from such problems (19-21).

A second key reason to focus on mental health needs in student curricula is that in doing so we can potentially prevent and minimise the negative future impacts of mental distress. Mental health problems that students experience early in their studies, imp--act upon their mental health after graduation (22, 23). A longitudinal study of Norwegian doctors, for instance, reported an increase in mental health problems that required treatment in 11% of graduates in the first year after graduation, and in 17% of students four years after graduation (24). Burnout, a marker of mental

distress, has been shown to be prevalent in medical doctors (2) and psychologists (25), and studies indicate that burnout starts during the early stages of study and increases over time (26).

A third central reason to focus on student mental health is that students who experience mental health problems seldom seek help (27). Garlow et al. noted that only 15% of students with moderate to severe depression or with suicidal ideation were receiving treatment (28). Less than half of Norwegian medical students who reported mental health treatment needs had sought professional help by the mid-point of their studies (8). Stress management programmes promoting mental health may also be a less stigmatising way to help students cope with their studies compared to advocating the use of therapy. Focusing on mental health may help to increase the likelihood of reaching students who are in need of such interventions.

A fourth reason to promote better mental health development is that mental distress can impact upon the personal development of students and affect their future careers as competent helpers. The personal characteristics of doctors and psychologists are important in patient encounters and can affect treatment outcomes (29, 30). In addition, if health professionals suffer from stress, burnout and depression, this can seriously impact upon the quality of care that patients receive (31-34).

Despite the importance of personal development and positive mental health, only limited emphasis has been placed upon such issues in the curricula of medicine and psychology. This failure is of concern given that studies have shown that empathy levels in medical students decline during the course of their studies (35, 36) – a decline that appears to coincide with the start of clinical training and patient encounters (37).

These four key areas of concern therefore strongly informed my research and motivated me to test an intervention for students which could positively influence their mental health and their ability to cope better with their studies.

Interventions to reduce stress among students

When we began to plan this study in 2008, only limited evidence about stress reduction interventions among students was available. Data from single studies, for instance, had shown some effects for some kinds of interventions, including mindfulness training (38-41).

In 2008, we identified four intervention studies that had investigated the effect of MBSR on students (38, 39, 42, 43). The first study was a wait-list controlled RCT with a sample of 28 undergraduate medical students (38). It showed that MBSR had a large effect on psychological symptoms, as well as students' sense of control and spirituality. However, the value of the

findings was limited by the high attrition level: only five of the 14 students in the control group were assessed at post-intervention. In addition, the facilitator of the study also had teaching responsibilities for the students. The second of the four studies was also a wait-list RCT, had a sample of undergraduate medical students (N=78), and reported a significant decrease in stress and anxiety and an increase in spirituality and empathy after the intervention (39). This study, too, had limitations: the assessment of the effect of the intervention, it may be argued, was compromised by the fact that the MBSR training was delivered as an elective session for which participants received study credits. Student evaluations of the course may have been biased by the fact that the post-intervention assessment was delivered only 15 minutes after the final mindfulness class. However, the validity of the study was enhanced by the very low level of attrition and by the replication of the results in the wait-list group.

The third study we identified was a non-randomised controlled trial with a sample of 133 second year medical students, in which the control group received a comparable intervention course on complementary medicine (42). The study showed a significant effect on mood disturbance in the MBSR group compared to the control group. The shortcomings of this study included the absence of participant randomisation and the use of only one outcome measure. The final study identified was a RCT comparing a shortened MBSR course (4 sessions of 1.5 hours each) to a comparable

relaxation course delivered to a control group. One hundred and four medical and nursing students participated (43). The study showed that, compared to the control group, the MBSR training had a large effect on mental distress and relaxation, and a differentially larger effect on rumination. The study was limited by varying levels of attrition in the groups, and limited follow-up (the results of only 81 participants were analysed at the post-intervention stage).

Summing up, there was a scarcity of studies identified and few that met the rigorous methodological criteria used in randomised controlled trials. Most studies lacked, for example, a description of the randomisation procedures, concealment of allocation, methods for the blinding of outcome assessors, and intention- to- treat analyses of the data. These weaknesses highlight the need for further well-designed intervention studies in this field.

While the number of studies of the effects of MBSR programmes has steadily increased, the last general review and meta-analysis of such programmes was published in 2004, and the most recent comprehensive search of the literature we was able to identify was completed more than a decade ago, in 2002 (44). We decided therefore that a systematic review and meta-analysis of randomised intervention studies using an MBSR programme should be undertaken (Paper I). Just one year after the publication of this first paper, the document had been downloaded 10,000 times – a result that clearly confirmed the depth of interest in this field.

As noted earlier, we were able initially to locate only a small number of studies investigating the effects of MBSR interventions. The absence of such research indicated that large, representative RCTs were needed in order to verify the effect of MBSR programmes for students, and to identify exactly which types of students could benefit most from such interventions. It was also clear that further investigation was needed to understand the psychological mechanisms of MBSR intervention effects.

Central concepts

This section explores some of the central concepts used in this thesis, including mindfulness, stress, coping, and personality. The discussion also outlines how these concepts relate to health and illness.

Mindfulness

Mindfulness is a concept that can be understood in a variety of ways. Interpretations rooted in western psychological traditions focus commonly on the mental faculties of awareness and attention. In Buddhist traditions, where mindfulness was first conceptualised, it primarily involves the faculty of awareness. Attention (understood to be 'concentration' is seen as a separate, distinct faculty (45). Although we all possess the ability to be aware and to pay attention, individual variations may occur in our ability and willingness to exercise such mental qualities (46).

Distinguishing between the attention and awareness dimensions of consciousness and other modes of mental processing – such as intentions, cognitions and emotions – is also possible. This is because, in addition to our bodily sensations and sensory stimuli, people are capable of being aware of their intentions, thoughts and emotions. Awareness, one can argue, is the background 'radar' of consciousness – in other words, it is a person's ability to monitor their inner and outer environment continually. Attention, in contrast, is the process of focusing our consciousness on a limited range of experience (47). According to this logic, mindfulness can be seen as enhanced attention to, and awareness of, what is happening in the present moment. As such, it can be regarded as an open, receptive and non-evaluative state of mind. Sometimes this state is referred to as a 'being' mode, as opposed to a 'doing' mode.

A 'being mode' is undoubtedly of importance to clever and ambitious students of medicine and psychology. Many work long hours to absorb large amounts of knowledge and to perform well in exams. Likewise, they are likely to experience moments in which they appear to be listening to friends but, internally, are so absorbed in their thoughts about the past or the future that they are unable to hear or recall what they have been saying. A 'being mode' enables people to stay more present during events as they unfold without labelling, categorising or immediately reacting to what arises. In patient encounters, this is of obvious importance.

In contrast to other forms of self-examination, like meta-cognition and mentalisation, which focus on the contents of thoughts and emotions and our relationship to them, mindfulness is primarily concerned with the quality of consciousness itself – in other words, of being aware of what is happening. The function of mindfulness is primarily perceptual and 'pre-reflexive' and gives clarity and vividness to our experiences. It stands in contrast to the less 'awake' state that we experience during the habitual and automatic functioning which forms so much a part of our daily lives. How exactly the mechanisms behind mindfulness work is not yet fully understood, and nor is whether these mechanisms depend on individual personality traits or coping styles.

John Kabat-Zinn, one of the first western researchers to conceptualise mindfulness, defined the concept as *the ability to pay attention to the present moment, on purpose and without judgement* (48). By allowing us to regard sensations, thoughts and feelings as 'objects' which can be observed directly without cognitive evaluation or elaboration, mindfulness enables people to achieve greater impartiality. It also reduces their automatic, habitual reactions to what arises in their minds and allows for more considered responses (48). Furthermore, mindfulness may foster greater openness and acceptance without allowing our direct experience to be clouded by our preconceptions (48). This may be especially important in decision-making in emergency high-stress situations. Mindfulness can also

foster non-reactivity, a quality that enables people to 'let go' of the thoughts and emotions that otherwise would trouble them unnecessarily (49). The most effective way of dealing with worry may well involve techniques that help an individual to attend to the present rather than the past and the future (50). For stressed students with high levels of conscientiousness and vulnerability, such skills may be of particular importance.

The relational aspects of mindfulness (how people relate to others and themselves) have always been central to contemplative traditions of mindfulness training. Studies within western traditions have shown that mindfulness training leads both to greater attention regulation and to increased self-compassion and empathy – facets that have been shown to independently predict mental health outcomes (51-53).

An additional important dimension of mindfulness is the process of insight. This is achievable through impartial observations of all sense impressions and mental phenomena, and an understanding of their fundamental characteristics, namely: 1) that they are transient, 2) that they will give rise to habitual reactions of aversion and attachment, which lead to suffering, and 3) that they do not contain any lasting separate identity, which we might call a 'self'. A recent study demonstrated that mindfulness predicted greater insight problem solving, and that the correlation between mindfulness and insight problem solving was strengthened through mindfulness training (54). Both the relational aspect of mindfulness and its

possible effect on problem solving are therefore potentially important to healthcare professionals and the delivery of healthcare services. The final key aspect of mindfulness that I wish to highlight is the ethical dimension. This has been an integral component of mindfulness traditions and requires people to live both mindfully and according to ethical standards. In our RCT, the training method used focused mainly on the attention, awareness and attitude aspects of mindfulness, although some compassion exercises were included too. Using an FFMQ questionnaire, we tried to capture data related to different aspects of mindfulness; including attention, awareness, and attitude, so that we could examine which of these aspects were affected by the mindfulness intervention. In addition, we included a measure in our study for 'empathy'. We hoped, thereby, to contribute to an understanding of the mechanisms of change associated with mindfulness training.

Mindfulness and health

Many philosophical, spiritual, and psychological traditions emphasise the importance of the quality of our consciousness to our health and well-being (55) but such issues have received little empirical attention. Partly this may be because the primary qualities of consciousness, namely attention and awareness, are ubiquitous and exercised by us all. However, in the last fifteen years, increasing interest has been given to dimensions of consciousness, particularly within the field of mindfulness research and

psychology. Although mindfulness, as I noted before, is based on ancient Buddhist traditions, it is the recognition that mindfulness can be taught within a non-religious context that has caught attention in the western research world (48). The understanding that mindfulness can have impacts upon a variety of health and well-being outcomes (44) has also encouraged research interest.

Being aware and attentive of the present moment may help to foster self-endorsed behavioural regulation and, in turn, help to improve mental health among students in higher education (56). By adding vividness and clarity to people's experiences, mindfulness may also contribute to well-being in a direct way. This association has been illustrated in experiments showing that focusing attention on the sensory experience of eating chocolate gives participants greater pleasure, compared to those who are engaged in a distraction task while doing so (47).

Open observant awareness and attention, it has been argued, may optimise self-regulation and well-being (57). This is because a state of relaxed attention enables the identification of needs, conflicts, and existential concerns. Converting needs, conflicts and concerns into conscious, recognised 'elements', it has been suggested, may allow for personal transformation and growth and have a positive impact on mental health. To date, however, few large, prospective empirical studies have investigated the psychological mechanisms that underlie the effects of

mindfulness training, and it is hoped that this study will help to contribute to knowledge in this field.

Theories of self-regulation often focus upon the role of awareness and attention in the maintenance of psychological and behavioural functioning. Self-determination theory (SDT) (56) states that awareness is crucial for choosing behaviours that are consistent with one's needs, values and interests. It is this understanding which underlies treatments that include mindfulness training for people with obsessive compulsive behaviour (58). Cybernetic theories may also help us to understand how mindfulness training may help to influence health. Conscious attention, it is argued, is key to the communication and control processes which underlie the regulation of behaviour (59). Biofeedback research, for example, has shown that conscious attention can be a key component in reducing unhealthy somatic conditions or symptoms of illness (47).

In this section, I have presented evidence showing that mindfulness training can improve self-regulation, decrease emotional reactivity and negative emotions, and help to increase positive emotions (60). These findings correlate with evidence showing how mindfulness training is linked to actual physical changes in the prefrontal cortical areas of the forebrain and the amygdala region in the midbrain. Although sustained, non-judgmental observations do not enable people to escape or avoid emotions such as anxiety, they may lead to a reduction in the emotional reactivity

that often accompanies unpleasant emotions. In doing so, they may help to promote health. By including measures of emotional distress, well-being, and mindfulness in our study, we were able to investigate whether mindfulness training in students would result in both increased mindfulness and better mental health and well-being.

Mindfulness, disease and illness

Early research indicated that mindfulness training could impact upon self-reported outcomes for illness and disease, such as pain, stress, anxiety and depression (61). Two general meta-analyses, for example, confirmed a moderate effect of mindfulness training on psychological outcome measures (44, 62) (although the analyses included few RCTs with student participants). Outcome measures for mental distress were therefore also included in our RCT.

The positive effects of an improved capacity to cope with mental distress have spurred interest within the field of mind-body medicine as well as within research related to stress, and it has been suggested that chronic stress may cause and contribute to illnesses such as cardiovascular disease (63). Significantly, research has shown that mindfulness is associated with – and may influence – stress-sensitive bodily processes. In a study of 500 psychology students, mindfulness levels were found to predict heart rate

variability (HRV) – a measure of the heart's ability to adjust to changing circumstances (64). Similarly, a recent study comparing the effects of mindfulness training and exercise on upper respiratory tract infections showed similar positive changes in the immune response of both groups. Significantly shorter episodes of infections and reduced time off work were also noted in the mindfulness group (65). It is therefore possible to contend, too, that mindfulness may influence disease processes. Data are limited regarding whether mindfulness may impact upon a disease once structural changes in the target organs of a disease are evident (66). However, it seemed pertinent in light of the evidence to focus on ways to prevent unhealthy stress levels among the students. A decision was thus taken to include an outcome measure of student stress (PMSS) when assessing the impact of mindfulness.

In summary, evidence has indicated how the ability to be aware of – and attend to – the present moment has implications for health and well-being. Research on stress has provided increasing insight into the relationship between mental and social factors and diseases (67, 68). Training the mind to achieve a balanced, relaxed and attentive mode, as the evidence suggests, may have positive health effects. We know that careers characterised by considerable inherent stress can compromise the mental health and subjective well-being of students. Testing the effects of

mindfulness training on health professional students, as we have done in our study, is thus particularly pertinent.

Stress and coping

Stress can be understood as a psycho-physiological state that arises when a person is confronted with a stressor (a threat, a harm or a loss, for example) which is perceived to endanger their health and well-being, and which is perceived to tax or exceed their ability to manage it (69). Coping can be understood as a response to stress, and may include efforts to prevent or diminish a threat, harm and loss or to reduce the associated distress (70). In this regard, a distinction can be made between disengagement and engagement coping. Disengagement or avoidance coping entails efforts to escape a source of stress and its related negative emotions. Examples of coping through disengagement include wishful thinking, substance abuse, denial, isolation, hiding emotions from oneself or others, fantasising, blaming others, and other forms of experiential, affective or behavioural avoidance. Such coping strategies may be effective in reducing negative affect in the short-term (nervousness, for instance, about an upcoming exam), but they do not help to support a person's health and well-being in the long-term (71). Avoidance may even be harmful: firstly, not dealing with a chronic stressor may lead to prolonged biological and psychological stress responses that may have

a number of harmful effects on a person's body and well-being (72). Secondly, avoidance and denial may result in an increase in intrusive thoughts about a stressor (70). Thirdly, disengagement coping strategies such as wishful thinking have been shown to be valid predictors of future mental health problems in medical students (23). Finally, the consumption of drugs or alcohol to avoid thinking about problems or to avoid experiencing associated negative feelings, is a coping strategy that can create problems of its own, including addiction (73). We assumed that mindfulness-based training would help to reduce avoidance and disengagement coping strategies, but this hypothesis has not yet been tested in a prospective study.

Engagement or approach/active coping responses, by contrast, are oriented towards a stressor or a person's reactions to a stressor (74). These responses include active attempts to change the stress-inducing situation or, alternatively, attempts to adapt to a stressor to create a better fit between oneself and the environment (70). Strategies include problem solving (active attempts to resolve the situation through planning, logical analysis, staying organised or implementing solutions), seeking emotional and instrumental social support (comfort, advice), and cognitive coping (identifying benefits arising from the situation or finding another way to approach a situation) (70). Engagement coping strategies are better predictors of

physical and psychological health outcomes compared to disengagement coping (71).

However, we do not know whether such coping strategies mediate the effects of MBSR interventions, or whether they can be moderated by such interventions. In our RCT, coping measures were therefore included as secondary outcomes. We expected that MBSR interventions would effect and/or enhance engagement coping strategies.

Personality

The personality of an individual is an important factor that may influence both a person's level of stress and how they respond to mindfulness training. The three main personality traits of neuroticism, conscientiousness and extroversion were therefore measured at baseline in all the students who participated in this study so that we could examine the relationship between their personality and the outcomes. Neurotic people tend to be anxious, self-conscious, moody and insecure (75). As has been shown, neuroticism results in an increased susceptibility to psychological distress: in a meta-analysis (76), a strong negative correlation was found ($r=-.51$, $SD=.07$, $N=2154$) between neuroticism and negative affect. Neuroticism also correlates positively with impulsivity and negatively with self-control (77). It has been demonstrated to predict stress in students

during medical school over a six-year period (78). As such, neuroticism may be understood to be a predictor of higher reactivity to stressors.

Conscientious individuals, by contrast, are likely to be dependable, responsible, rule abiding, controlling and achievement-oriented (75). Self-discipline is central to this personality trait and is characterised by deliberateness and effective responses rather than reactions based on impulse or habit (76). In some studies, conscientiousness has been regarded as an adaptive trait for physicians (79), while others have viewed it as stress-evoking (80). In longitudinal studies of medical students and doctors, conscientiousness predicted medical school stress in students over a period of six years (78) but did not predict life quality among doctors over a ten-year period (18).

Extroverts tend to be talkative, social and assertive (75) and these traits have been linked to subjective well-being and positive emotionality (81). However, the need for excitement and the need for stimulation are also characteristic of extroversion (76) and may therefore influence the effect of mindfulness training.

Particular personality traits do not exert an influence in isolation relative to others. Studies which have examined the combined effect of the three key personality traits on stress in medical students (82) and medical doctors (78), have shown that students with high scores on neuroticism and conscientiousness and low scores on extroversion, experienced more stress.

Students with high scores for extroversion and low scores on the other two traits were shown, by contrast, to be protected against stress.

Personality and mindfulness

Personality traits are well-recognised dispositional constructs. The trait of mindfulness may also be considered as such, in that it is a way of relating to oneself and the world. When attempting to understand what a new concept is, and when assessing its construct validity, one often tries to relate it to other constructs (83), such as personality. The results of individual studies may be divergent. Testing the relationships between constructs can therefore be more rigorously undertaken with meta-analytic procedures. The data from one meta-analysis reported that the strongest negative correlation (an estimated mean true score) identified in the study was between mindfulness and neuroticism (r=-.58, SD=0.12, N=3,309) (76). The highest positive correlation found in the same study was between conscientiousness and mindfulness (r=.44, SD=0.10, N=895). Extroversion, in contrast, was found to show only a small correlation with mindfulness (r=.15, SD=0.09, N=1,674). I contend therefore that further research is needed on how mindfulness might be correlated with personality traits to help us to understand more about the relationship between personality and mindfulness. It is hoped that this study will also help to contribute to deeper knowledge within this field.

Another way to explore the interplay between personality and mindfulness is to examine the moderating and mediating roles of mindfulness in relation to personality traits and outcomes. One study of undergraduate psychology students looked at the role of mindfulness as a moderator of the relationship between neuroticism and the outcomes of anger and depression (77). The study reported that both neuroticism and mindfulness independently predicted both anger and depression and that the neuroticism-outcome relations were weaker among individuals with high mindfulness scores. The authors of the study proposed that mindfulness could be a potentially protective factor in relation to the increased stress-reactivity that neuroticism typically entails. This claim, in turn, has been supported by intervention studies which have shown reductions in depression relapses following mindfulness training (84). Our study aimed to broaden knowledge in this field still further by investigating the relationship between personality traits, mindfulness, and mental health outcomes in a student population.

The mediating role of mindfulness has been explored in several studies, although without conclusive findings. In two studies with undergraduate students (85), the trait of mindfulness was found to be a mediator in the relationship between neuroticism and both impulsivity and self-control. Higher levels of mindfulness were associated with lower levels of impulsivity and with higher levels of self-control. A study with a sample of

35 experienced mindfulness practitioners and 35 matched controls who did not have previous experience of mindfulness (86), showed that mindfulness mediated the relationship between the amount of mindfulness practice and the scores on the five key personality traits (extraversion, agreeableness, conscientiousness, neuroticism, and openness).

It is possible, too, that the effects of MBSR interventions may also interact and affect personality traits. The interaction between neuroticism and mindfulness training on the outcomes of stress and distress is examined in Paper III of this doctoral submission. Our study will continue to explore the issue of mindfulness as a mediator of the outcomes when follow-up data for the RCT becomes available at a later stage. This will help us examine whether mindfulness may influence the expression of personality traits and possibly change them over time (87, 88).

Research aims and questions

The overall aim of this thesis was to study the effect of MBSR on the mental health of medical and psychology students and to identify individual factors involved in such effects. The specific research objectives were:

1. To assess, using a meta-analysis of data from randomised controlled trials, the effectiveness of MBSR interventions in improving health, quality of life, and social functioning in adults (Paper I).

2. To test the hypothesis that an MBSR programme could enhance the mental health of medical and psychology students as measured by multiple dimensions of psychological health and well-being (Paper II).
3. To test whether the intervention effects were influenced and/or moderated by individual factors (gender, personality, mindfulness practice, baseline mindfulness and social support), and organisational factors (university, course, class, and instructor). (Papers II and III).

Materials and methods

Study design

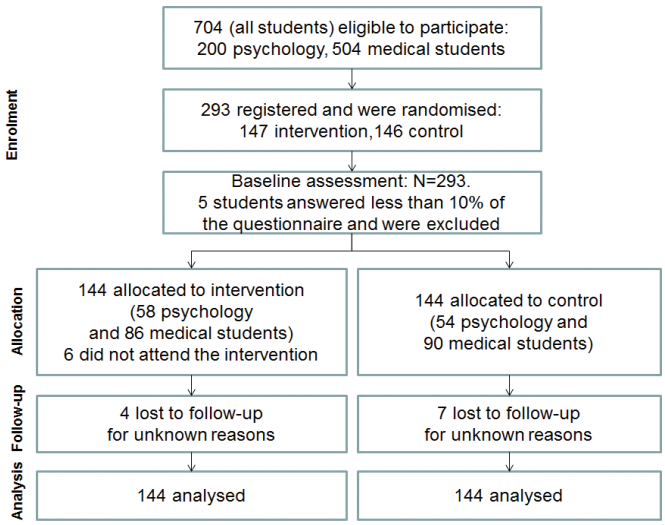
The first part of the study was a literature review and meta-analysis based on the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (89). Work on the first stage of this study began in 2009 and the final literature search was completed in September 2010. The second part of the study was a two-centre randomised controlled trial which assessed the effect of a seven-week MBSR programme on 288 medical and psychology students at the Universities of Oslo and Tromsø, Norway. The students participated in both 2009 and 2010 and, according to the study protocol (90), will be followed until one year after they qualify, in order to evaluate the possible long-term effects of the mindfulness training. Quantitative baseline and post-intervention self-reported measurements

were submitted online by participants. In addition, focus group interviews were conducted during the intervention and again at two years by the principle researcher responsible for the Tromsø component of the trial. An analysis of these qualitative data, as well as additional data collected two and four years after the intervention, will be published as part of her PhD.

Recruitment of students for the RCT

Five classes of second term (there are two terms in each study year) medical students and five classes of second and third term psychology students were given a 15-minute in-class presentation inviting them to participate in the study. In addition, the eligible students received an email with information about the study (Appendix 1). Psychology students in their third term of study were included as potential participants at the University of Oslo, because many students are exempt from the first year of psychology. This was not the case at Tromsø University: here, all the participants were second term students who came from two medical and two psychology classes. Figure 1 describes the study recruitment and dropout from the enrolment phase through to the analysis. The gender distribution of the students who enrolled in the study was 76% female and 24% male, while the distribution in the eligible sample was 70% female and 30%. The enrolment of female students was higher in both the medicine and psychology courses at both the University of Tromsø and the University of Oslo.

Figure 1. Recruitment and dropout



Randomisation and concealment of allocation

Study registration took place online after the students had confirmed that they had read the information about the study and had consented to participate. After the students had registered and completed the online questionnaire, the Head Technician at the Norwegian Knowledge Centre for the Health Services randomised the students either to the intervention group or to the control group, using a Java-based random number generator program. The randomisation of students in each class was performed separately because the classes entered the study at different times. No

stratification by gender was undertaken. Study participants were sent an email two weeks prior to the intervention to inform them of their group allocation.

The Head Technician at the Norwegian Knowledge Centre for the Health Services also assigned each participant an identity (ID) number to ensure that the data remained anonymous, and a unique number was assigned to each of the online questionnaires. Only the Head Technician had access to the data showing the link between the student identities and the ID numbers, and he was otherwise not involved in the study. Those who analysed the data therefore did not know the identity of the students.

Ethics

Participants were informed that they could withdraw from the study at any time. They also had the opportunity to contact the principal researchers in Oslo and Tromsø with queries or if they experienced any ill effects caused by their participation. In Oslo, several students used this opportunity to clarify questions about the study. No reports of adverse effects were received. The Regional Committee for Medical and Health Research Ethics, Norway, and the Norwegian Data Inspectorate approved the study (Appendix 2).

Completeness of data

Five students registered but, for unknown reasons, failed to fill in more than 10% of the questions in the online protocol. These participants were excluded from the study. The design of the online protocol required the participants to answer all the questions on each page before they could proceed to the following one. Most of the protocols were completed: only 11 were missing at post-intervention. Data were therefore missing for only 6% of the sample.

The intervention – an MBSR course

I completed a three-month internship and instructor-training course in 2002 at the Center for Mindfulness in Medicine, Health Care and Society (CFM) – an institute based at the Medical School at the University of Massachusetts. The Center's founder, Dr. Jon Kabat-Zinn, developed an eight-week MBSR programme in 1979, which has since been taken by more than 20,000 patients and 5,000 healthcare personnel at the facility. With permission from the CFM, the MBSR programme manual was translated into Norwegian and used in a randomised wait-list controlled study in which 149 patients in primary care who were suffering from stress and chronic illnesses participated (91, 92). Adjustments to this programme for the student population were based on previous intervention studies that had successfully

used shortened versions (43). Our meta-analysis showed that the length of the MBSR programmes did not predict the outcome effects (93).

A group interview was also conducted with junior and senior medical and psychology student representatives at the University of Oslo. Their input helped us when deciding on the duration of the weekly classes, the total programme length, and the amount of home exercise it would be wise to ask the students to do. Based on their feedback, we revised the programme and reduced the number of weekly meetings from eight to six, and the length of each weekly meeting from 150 minutes to 90 minutes. A full day of mindfulness exercises was held in week seven of the training. Following the consultation, the recommended amount of home exercises was reduced from 45 to 30 minutes, 6 days a week. The themed progression of the original programme was maintained, as was the order in which the different types of exercises were introduced. Appendix 3 provides a detailed content description of each class.

Instructor qualifications

The PhD candidate conducted the MBSR courses at the University of Oslo. He has more than 40 years of mindfulness practice and received his training in MBSR at the Center for Mindfulness. In one of the courses, a female psychologist who had also received training from the CFM participated as a co-instructor. In two courses, a male psychology student

with teacher training from the CFM and from Bangor University in the United Kingdom also co-instructed. Each co-instructor had practiced mindfulness for four years. The local Principal Project Manager ran the MBSR-courses at the University of Tromsø. She has practised mindfulness for six years and is a trained MBSR instructor from the CFM. Two psychiatric nurses – one a trained MBSR instructor from CFM –participated as co-instructors. Both have practised mindfulness mediation for several years.

Outcome measures

Papers II and III describe the outcome measures of the study and additional information is provided here. The outcome measures were divided into two categories: measures for mental health and measures for personal development.

Mental health outcomes

Mental distress

Three different outcomes assessed mental distress. The first was the *General Health Questionnaire* (GHQ). The GHQ has been translated into and validated in more than 40 different language versions, and there are five versions of the GHQ that vary in terms of the number of items included (12, 20, 28, 30, and 60). In this study, the 12-item version was used (Paper II lists the response categories).

The concept of mental distress refers to an end state and is a discomforting subjective condition. In the GHQ literature, degrees of distress are seen as referring to a degree of burden and as indicating a lack of coping (94). Importantly, mental distress as has been argued, must be distinguished from stress, which refers to a subjective discomforting experience related to internal or external stressor(s). The 12-item version of the GHQ has been validated internationally and for use with Norwegian student populations (94, 95). Examples of the included items are: 'Able to concentrate', 'Lost sleep over worry', and 'Felt constantly under strain'. We used a sum score and the Cronbach's alpha for our sample was .90.

The second measure of mental distress used in our study was a 5-five item version of the *Hopkins Symptoms Checklist* (SCL). The SCL examines symptoms of anxiety and depression and has been shown to have good specificity (82%) and sensitivity (96%) for detecting mental distress (96). A Norwegian population study showed that the 5-item version of the SCL performed nearly as well as the full 25-item version in detecting mental distress (97). The SCL has been used in a Norwegian MBSR intervention study (92) (a study of Norwegian medical students) (98), and in an intervention study of coaching for Norwegian doctors who had burnout (99). The SCL includes five questions to assess how much a person has experienced, or been bothered by, the following symptoms during the last two weeks: 1.`Feeling fearful', 2.`Nervousness or shakiness inside',

3.`Feeling hopeless about the future', 4.`Feeling blue', and 5.`Worrying too much about things'. Each of these items is measured on a five-point scale, ranging from 'Not at all' (0) to 'Very much' (4). The total sum score, ranging from 0 to 20, indicates the level of a person's mental distress. Because the SCL results correlated highly with the GHQ (r=.78), and because the second item in the SCL was also included in the subjective well-being scale used in this study, the results for the SCL were not used in our analyses (see Paper II). For the sake of completeness, however, the findings of the SCL are presented in the results section of Paper II. The Cronbach's alpha for the SCL study was .88.

The third measure of mental distress used in this study was the 15-item *Maslach Burnout Inventory – Student Survey* version (MBI-S), a cross-culturally validated survey with good psychometric properties (100). This version has been tested on pre-clinical and clinical medical students (101). A sum score was used for the categories (see Paper II for details about the dimensions and response categories used) – an approach recommended when using and measuring burnout as a scale dimension (102). The forward-backward translation of the Norwegian version was completed at the University of Tromsø. The Norwegian version had not been used prior to this research, but a factor analysis of our sample (Appendix 4) showed very similar results to those obtained from tests using the original scale. The Cronbach's alpha for the sum scale in our sample was .90.

Student stress

Study stress was measured using the 13-item *Perceived Medical School Stress* scale (PMSS) (103), with one item adapted for cultural reasons because it related to elective periods and clerkships not relevant in Norway (17). This scale examines different areas of student stress such as academic demands and endurance, as well as stress related to recreation, economic status and housing. The PMSS assessment scale has been shown to have adequate predictive validity for mental health problems in medical students (8, 17), and in medical professionals after graduation (23). In our study, the PMSS scale was adapted by removing the word 'medical' from the terms 'medical study' and 'medical training' so that it would be suitable too for psychology students (Paper II lists all the response categories). The Cronbach's alpha value for our sample was .79 (.81 for psychology students and .78 for medical students).

Subjective well-being

Subjective well-being (SWB) was measured using a short version of a Norwegian *SWB scale* (104) which has been used in several studies (105, 106). This scale has been shown to have good psychometric properties and has been validated for use with both Norwegian student and adult populations (105). The index of this scale is a sum-score of four items: 1. 'When you think about your life at present, would you say you are mostly

satisfied with your life, or mostly dissatisfied?' (This first question has been used in other studies of Norwegian medical students, doctors, and in population surveys) (7, 18, 107), 2. 'Are you usually happy or dejected?', 3. 'Do you mostly feel strong and fit or tired?', and 4. 'Have you suffered from nervousness or shaking inside?' (see Paper II for a list of the response categories). The Cronbach's alpha for our sample was .81.

Personal development outcome measures

Mindfulness

Exactly which facets constitute mindfulness remains the subject of ongoing debate (76). Multiple trait inventories have been developed to measure mindfulness, and research has shown that these inventories have moderate to large correlations with each other (46). Some researchers (47) have limited the concept of mindfulness to include only a person's ability to attend to – and be aware of – what is happening. Others, such as Baer (46), in addition to including the ability to meet what arises with non-judgement and non-reactivity, have also included the facets of observing, describing, and acting on what one is aware of. Baer's construct, known as the *Five-Facet Mindfulness Questionnaire* (FFMQ), was used in our study (see Paper II for further details).

Among those who do not meditate, studies have reported low inter-correlations between some facets (such as between observing and acting with awareness) and negative correlations between the facets of observing and being non-judging (46, 108). However, when people have received mindfulness skills training (109), strong positive correlations have been found between these facets. Such findings have led some researchers to regard mindfulness more as a set of skills than a general trait (76). In our study, we used the sum of the five facets as the primary outcome measure. In instances in which this change was significant, secondary analyses involving the individual facets were undertaken (Paper II). The Cronbach's alpha for the FFMQ sum scale was .79 (see Paper II for the alpha values for the individual facets, response categories, and validation details).

Empathy

The 20-item *Jefferson Empathy Scale* (Health Personnel version) (JSE-HP) which measures empathy was also used in our study. Twenty questions are presented on a seven-point scale that ranges from 'strongly disagree' to 'strongly agree', and empathy is measured using a summed score. Developed for studies of medical students and health professionals, the scale has been shown to have good psychometric properties (110), and can predict empathic behaviour in students after they have qualified as a doctor (111). Studies in which this scale have been applied have also shown that empathy decreases in medical students in the latter stages of their clinical

curriculum (36, 112). A similar version of the JSE for students used the same factor structure and demonstrated very similar results to the reliability tests undertaken for medical students (110, 112): students, in this instance, were asked what they thought was important for doctors to do in relation to their patients. The Health Personnel (HP) version of the JSE was chosen for use in this study as doing so made it easier to apply the tool to both medical and psychology students. In our version, the students were asked to respond to the questions as if they were treating patients. Another reason for choosing the HP version is that this will allow us to use the same scale inventory after the students have begun their clinical practice training, and again after they have qualified.

In agreement with Dr. Hojat who devised the original JSE-HP, the material was translated into Norwegian using a standardised two-way procedure (forward-backward translation by two bilingual Norwegian/English speakers) and then tested on five student population samples (Appendix 5). The translated questionnaire is now the official Norwegian translation of the JSE-HP and has been posted on the Jefferson Medical College website (113). The Cronbach's alpha value for the sum scale in our student sample was .78. A full factor analysis of the translated version in our sample will be completed by the Tromsø research team involved in this mindfulness trial.

We expected that the MBSR training would have a long-term effect on the development of empathy in students during the course of their studies.

Pre- and post-intervention measurement values of empathy were not included in Paper II but, for the sake of completeness, are shown in the Summary of Results section of document.

Coping

The expectation in this study was that the mindfulness training would influence the way students coped with their studies and their life situation. Coping was not regarded as a primary outcome and was therefore not reported in Paper II. Again, for the sake of completeness, the relevant figures related to coping are shown in the Summary of Results section of this document. An article about mindfulness, personality and coping is also in progress.

Coping was measured in this study with the 42-item *Ways of Coping Checklist* (WCCL) (114), a tool which has been shown to have good psychometric properties (114). The checklist consists of five coping dimensions: 'problem focused', 'seeking social support', 'self-blaming', 'wishful thinking' and 'avoidance'. Each dimension is measured using a 5-point Likert scale that ranges from 0 ('does not describe me at all') to 4 ('describes me most of the time'). This checklist has already been used in Norwegian student populations (7). Factor analyses indicated a three-factor coping solution that included being problem focused, seeking social support, and using avoidant modes of coping. A principal component analysis

(Appendix 6) of our sample indicated that participants used the same three-factor structure of coping. The Cronbach's alpha values in our sample were .79 for problem focused, .86 for seeking social support, and .82 for using avoidant modes of coping.

Personality

Personality was measured using the 27-item version of the *Basic Character Inventory* (BCI) developed by Torgersen (115). This measurement tool is rooted in psychodynamic personality theory, and the factor structure of the inventory has been tested on both men and women, in clinical and non-clinical populations, and in different countries (116). The inventory has previously been tested in studies of Norwegian medical students (78) and Norwegian doctors (117). The BCI measures three main personality dimensions, namely neuroticism, conscientiousness and extroversion – dimensions which closely resemble the classic three key personality traits (noted earlier) (118, 119) that some have argued are strongly biologically determined (120). Each dimension of the BCI, in turn, includes nine items, which are statements scored as either 'true' or 'false'. The Cronbach's alpha values for the dimensions were .75 for neuroticism, .68 for conscientiousness, and .77 for extroversion (see Paper III for a detailed discussion of the response categories and dimension ranges).

Demographic factors

In addition to measuring participant age, gender, marital status, and number of children, additional measured factors included significant life events and the degree of social support received.

Negative life events in the last year have been shown to be negatively correlated to mental health and life satisfaction in health professionals and students (8, 18, 26, 121). Five life events questions were included. Three questions related to negative life events, namely:
a) serious disease/accident/hospital admission, b) divorce/separation/ broken relationship, and c) serious illness/death of family member or close friend.

Positive life events have been shown to be negatively related to burnout in medical students (26), and two items were included, namely: a) getting married, and b) having a child. Each question had a score for 'having' (1) or 'not having' (0) experienced these events in the last year.

Perceived social support has been shown to influence subjective well-being (18), and was measured by five questions that have previously been used in Norwegian studies of medical students and doctors. The five questions measured: a) frequency of contact with close friends, b) appreciation from friends outside family, c) the presence of warm and caring confidents, d) the degree of affiliation for groups, and e) anticipated support if the participants should fall ill. All items had five response categories: higher scores represented higher levels of experienced support. The items

were summed to one variable with a possible range from 5 to 25. The resulting Cronbach's alpha value for our population was .67 (a similar value of .70 was reported in an earlier study (18)).

Programme fidelity and compliance

The PhD candidate who led the classes in Oslo, and the PhD candidate who ran the classes in Tromsø, ensured programme consistency primarily through the joint development of the course programme. When running the courses for the first time the two candidates conferred by telephone each week. A specified written programme was developed for each class, including specified home assignments, a course book, and a CD with guided mindfulness exercises. The students brought the course book to the classes and made notes of their home assignment experiences in it.

Compliance was measured by noting participant attendance and by questions about the frequency and length of the mindfulness practice during the last month.

Statistical methods

This section provides additional information on the methods used to analyse the results in Papers I to III.

Paper I: Both the protocol and the review for the meta-analysis were created using RevMan, a software program for reviews and meta-analyses

that follows the format for Cochrane systematic review protocols (89). Data from the individual trials were combined in a meta-analysis. Doing this enabled us to calculate standardised mean differences and a Hedges' g effect size for the differences in these means. These calculations took into account the number of participants in the intervention and the control groups. The reported outcomes from all the included studies (on average five outcomes per study) were entered. We would otherwise had to have chosen only some of the selected outcomes. Because the multiple outcomes were measured on the same persons in each study, the outcomes are highly correlated. In order to calculate an average effect size estimate from each study with the correct standard errors, a newly developed statistical technique for calculating robust standard errors was applied (122). This technique results in smaller standard errors by reducing the common error variance from multiple outcome measurements taken from the same persons, and only results in minor changes in the calculated effect sizes. Tipton, who co-developed this method, was a member of the team who undertook the meta-analysis in this study and the robust standard errors were calculated by her using the statistical software program *R*. The strength of the evidence emerging from the meta-analyses, was assessed using the GRADE tool for grading the certainty of the evidence (123).

Paper II: Multivariate analyses of covariance (MANCOVA) were applied to the multiple dependent outcome measures to evaluate the effect of the

intervention. Bonferroni adjustments were made to the alpha level of .05 to test whether the significance level was appropriate for all sets of outcomes in the analysis. A MANCOVA analysis forms part of the General Linear Model family of regression analyses which model mean responses over time, and we checked the assumptions of normality for the distribution of variables within groups. In addition, the independence of the covariate and the treatment effect (the covariate had the same distribution in both the MBSR group and the control group), and the homogeneity of regression slopes was tested using scatterplots (the relationship between the outcome variable and the covariate were the same in the MBSR and control group).

To test whether course attendance and home exercises predicted outcomes in the MBSR training groups (Paper II), multiple linear regression calculations were made after checking the multicollinearity and heteroscedacity of the model's assumptions.

Because the students came from different classes belonging to different studies and universities, multilevel mixed linear regression analyses were applied. When class, study course or universities, as random factors, were found to be non-significant, they were removed from the model.

Paper III: In order to demonstrate the moderation of a treatment effect, the following conditions must be met: firstly, the moderator must be a pre-randomised characteristic that varies within the study population (53). All the variables in this study met this criterion. Secondly, the moderator

must be uncorrelated with the predictor thereby allowing for the interpretation of the interaction term (124) – this means that the level of the moderator must not differ across the treatment conditions. For this reason, we tested this criterion as part of the randomisation check. Thirdly, the effect of the intervention on the outcome must change as a function of the level of the moderator variable. This relationship was tested using a statistical test of moderation proposed by Baron and Kenny (1986): assuming that there is a linear, gradual change in the effect of the predictor which depends on the level of the moderator, moderation can be assessed in a multiple hierarchical regression by including the product of the moderator and the predictor variable as an interaction term. Some researchers have recommended raising the conventional alpha level of .05 to .1 when probing for interactions (125). Doing so increases the power of the test, but it may also inflate type 1-error rates. The traditional level of .05 was therefore retained in our study.

An interaction term which is found to be significant indicates that the effect of mindfulness training is dependent on a pre-treatment variable (moderator). To explore the moderation effects at different levels of the moderators in the control and intervention group, graphs were made displaying the effect of mindfulness training on the outcome variable at different levels of the moderators (Paper III). The Johnson-Neyman (J-N)

technique was used to identify which levels of the moderators determined whether the moderation was statistically significant (126).

Testing moderation using simple slopes with a -1 and +1 SD for the moderator variable is a useful technique when the dependent variable, the primary predictor, and the moderating variable are all continuous. However, in our case, the predictor was dichotomous (control vs. intervention) – the graphs in Paper III therefore display the full range of moderation in both the control and intervention groups.

Methodological issues

This section discusses a number of methodological issues that were not addressed in Papers II and III. Issues related to the meta-analysis in Paper I are also discussed.

Study design

The RCT design used in this study has the advantage of reducing the effects of unknown confounding factors, as the randomisation process should distribute these evenly across both groups. We did not stratify the randomisation procedure for gender and, by chance, we ended up with a significant difference in the number of male students in the control and the intervention group.

Randomising students within each class, instead of choosing entirely separate classes for the intervention and control groups, carries a potential

risk of contamination over time. Students, for example, who have positive experiences of a mindfulness intervention, are likely to communicate this to classmates in the control group who may, in turn, begin to practice. In order to evaluate this potential risk, students in both classes were asked to report, each time they filled in their questionnaires, how often they practised mindfulness exercises and whether they had participated in a mindfulness-training course. This information helped us to assess the degree of contamination at follow-up. Furthermore, subgroup analyses will be run at future follow-up analyses to see if participants in the control group who started to practice mindfulness report differently on the outcome measures compared to the rest of the control group.

Psychometric considerations

This study used only self-reported psychometric measures, which are susceptible to problems such as memory and response bias. Specific problems related to the measurement of coping and mindfulness also need to be considered. It is unclear, for example, if semantic knowledge about a person's own tendency to be mindful accurately reflects the quality of their attention in real time (127). Furthermore, self-reported assessments of coping can be influenced by the tendency to aggregate across events when answering general questions about how one has met different challenges. In

addition, a person's lack of insight into their own reactions when answering such questions may also bias the results (128).

Reliability is the extent to which measurement results and data are reproducible. This reproducibility depends on the characteristics of the items measured (internal consistency), on the ability of the measurement method to produce similar results when applied by different people (inter-rater reliability), and the degree of consistency that tests reveal across time (test-retest reliability). The achievement of internal consistency was deemed to be the most important test of data reliability in this thesis. The evaluation was measured using a Cronbach's alpha coefficient – an expression of the percentage of the variance in an index which can be accounted for by an underlying phenomenon. A value of .70 is generally regarded as acceptable. Cronbach's alpha values for the variables used in this study were higher than .70, except for the personality trait conscientiousness (.68) and perceived social support (.67). Cronbach's alpha values tend to increase with the number of items included in an instrument, and this may account for instances in which the alpha values were found to be low.

The **validity** of an instrument or test is the extent to which it measures what it is intended to measure, for instance relative to a 'gold standard' instrument or test. Important aspects of **test validity** include construct validity, content validity, and criterion validity. *Construct validity* is the extent to which the response to one rating scale correlates with related

scales (convergent validity) and unrelated scales (divergent validity). *Content validity* refers to whether the content of the instrument matches the content domain associated with the construct; criterion validity enables us to compare the measurement with other measurements of the same phenomenon. The RCT in our study used two questionnaires (a GHQ and an SCL) to assess mental distress. The findings from both questionnaires were highly correlated (r=.78), indicating good criterion validity. Most of scales used in our RCT have already been validated in student populations, but the MBI-S version and the JSE-HP have not yet been validated in Norway. This makes conclusions regarding the validity of these scales less certain.

Both the internal and external validity of a study will determine its overall **experimental validity**. The internal validity of a study refers to the degree to which conclusions about causal relationships can be drawn (for example, about the cause and effect of an event), and is shaped by factors such as the measures used, the research setting, and the research design. In our study, randomisation procedures were followed, as these have been shown to improve the accuracy of assessing the effects of an intervention. Confounders and sources of bias that may influence a study's internal validity are examined in more detail in the following section.

Circumstances and events *external* to the study may also affect research findings. The effects of an intervention, for example, may be influenced by the age of the participants and the effects of ageing over time,

if a study progresses over a long period. The concept of external validity can be understood as the degree to which the findings can be generalised *beyond* the included sample. In our study, the external validity was increased by the high response rate, the inclusion of several classes of both medical and psychology students, testing the effects at two different universities that had different study curricula, and by using different course instructors. We believe that our findings are therefore generalisable to other students of psychology and medicine at least in Nordic countries. We acknowledge, however, that the self-selection of 40% of the eligible students into the study, and a lack of information (demographic/personal/motivations for participation) about the other 60%, may decrease the external validity of the study. In addition, our research occurred within a particular cultural and historical context. Whether our results will be generalisable to future student populations is uncertain.

Bias

Different sources of bias may influence the results of scientific studies. The meta-analysis and discussion of RCTs related to mindfulness (Paper I) highlights potential sources of bias, many of which were applicable to our mindfulness intervention study (Paper II and III). In addition, forms of selection bias may also influence the results either, as in our study, through the self-selection of the students that chose to participate, or through the

failure of some participants to answer post-intervention questionnaires. Using a self-selection process may have resulted in our study sample containing people who had higher levels of stress/distress and may thus have augmented the effects identified. Students who participated could, for example, have been more motivated to do the mindfulness training if they were already stressed. Students in the control group who had higher stress levels may also have been more likely to become worse as time passed. On the other hand, it could be argued, this potential selection bias may have decreased the between-group effect of the intervention because students in the control group would have been more likely to start practising mindfulness. Reported home exercises, as we noted, did in fact increase in the control group from baseline to the post-intervention stage.

Attrition in our study was very low and is unlikely to have been a factor that affected our findings. The high response rate may have been encouraged by students being offered a book voucher upon completion of the study questionnaires both pre- and post-intervention. The administration of the questionnaires online may also have contributed to the high response rate, as the electronic self-completion of questionnaires is typically preferred to the self-completion questionnaires on paper (129).

Paying students to participate can result in reporting bias but we suggest that such a bias would have affected the participation both in the control group and the intervention group. Study bias may also have been

caused by using only self-reported measures. As has been shown, self-reported measures are susceptible to memory and response bias. Cognitive dissonance can also introduce a placebo bias if participants believe that an intervention can help (130). It is possible, too, that students may have reported positive effects without actually experiencing any.

Self-reporting measures can also be subject to demand characteristics (i.e. when participants attempt to please an investigator). This was a potential source of bias in our study given that the main study investigators were also running the intervention classes (131). The respondents may also have been affected by the perceived social desirability of certain answer categories, and been motivated to select answers that they believed would create a more favourable impression. Medical students, as research has shown, are particularly 'on guard' if questions in studies relate to mental health concerns (27), although such bias in responses to mental health questionnaires can be reduced if self-administration is used instead of face-to-face administration (132). Whether the influence of perceived social desirability was reduced by using computer-based questionnaire administration instead of pen-and-paper responses is uncertain (133). Although a large study of adolescents conducted in Belgium, showed that the mode of administration did not have a significant effect on responses to the majority of questions related to lifestyle behaviours, several questions about feelings/affective states elicited more apparently socially desirable responses

when answered on paper instead of a computer (134). To avoid the inherent risk of bias in self-reported measures, we could have used biological markers of stress as well as laboratory tests of attention and emotional control to strengthen the trial.

Ethics

The Steering Committee, which oversaw the RCT study, consisted of professors of Medicine and Psychology at the Universities of Oslo and Tromsø. To ensure that their involvement was unbiased and independent, members of the Committee had no role in the actual running of the intervention, and the study was conducted outside the normal curricula.

A group interview with medical and psychology student representatives (who did not take part in the trial) was carried out prior to the start of the study. This enabled us to get their feedback on how best to adjust the intervention to fit in with the curricula, and to get their input on the design of the trial.

To ensure the confidentiality of the participants, the Head Technician at the Norwegian Knowledge Centre for the Health Services assigned each participant an ID number which was attached to their online questionnaires (for further details, please see the Ethics section of this thesis).

The trial was approved by Regional Committee for Medical and Health Research Ethics, Faculty of Medicine, University of Oslo, Norway and the Norwegian Data Inspectorate, and was designed according to the

recommendations of the Trial Protocol Tool developed by the EC-funded project, Pragmatic Trials in Health Care (Practihc) (www.practihc.org). Before the trial started, the protocol was published on the website ClinicalTrials.gov under the identifier: NCT00892138 (90).

Summary of results

This section contains the shortened abstracts from Papers I, II and III. Additional results issues related to the study protocol are also presented: these data were not presented in the original papers.

Paper I

Mindfulness based stress reduction (MBSR) for improving health, quality of life, and social functioning in adults.

Objectives

Evaluate the effect of mindfulness-based stress reduction (MBSR) on health, quality of life, and social functioning in adults.

Search strategy

We searched all relevant databases in July 2008 and again in September 2010.

Selection criteria

Randomised controlled trials on all target groups were included

Results

We identified 31 RCTs and 26 were used for the meta-analyses (N=1,456). The post-intervention Hedges' g effect sizes were as follows: for measures of anxiety 0.53 (95% CI = .43, .63), for depression 0.54 (95% CI = .35, .74), and for stress/distress 0.56 (95% CI = .44, .67). The overall effect size post-intervention for the combined outcome 'mental health' was 0.53 (95% CI = -.43, .64). Heterogeneity was low and the tau square-values (for between-study variance) ranged from 0 to 0.03.

Effect sizes for the combined mental health outcomes were similar across the range of target groups: 0.50 for clinical and 0.62 for non-clinical populations. The effect sizes for mental health correlated positively with course attendance, and decreased with follow-up time.

Conclusions

MBSR has a moderate and consistent effect on a number of measures of mental health for a wide range of target groups. There is a paucity of data on long-term effects.

Paper II

Mindfulness training for stress management: A randomised controlled study of medical and psychology students

Objectives

To examine the effects of a seven-week Mindfulness-Based Stress Reduction (MBSR) programme on mental distress, study stress, burnout, subjective well-being, and mindfulness in medical and psychology students.

Methods

Two hundred and eighty-eight students (mean age = 23 years, 76% female) from the University of Oslo and the University of Tromsø were allocated randomly to an intervention or control group. The control group continued with their standard university courses and received no intervention. Using blinded assessors, participants were evaluated using self-reported measures both before and after the intervention.

Results

A moderate effect on mental distress (Hedges' g 0.65, CI = .41, .88), and a small effect on both subjective well-being (Hedges' g 0.40, CI = .27, .63) and the mindfulness facet 'non-react' (Hedges' g 0.33, CI = .10, .56) was found. Attendance and reported mindfulness exercises predicted these changes. Only female students showed significant effects. Additionally, only female students reported reduced study stress and an increase in the mindfulness facet 'non-judge'.

Conclusion

The present study shows that teaching medical and psychology students to relate mindfully to current internal and external stimuli can decrease mental distress and increase well-being.

Paper III

Does personality moderate the effects of mindfulness training for medical and psychology students?

Objectives

To investigate whether baseline personality factors (neuroticism, conscientiousness and extroversion) and baseline mindfulness moderated the effects of a seven-week MBSR programme on mental distress, study stress, and subjective well-being after the intervention.

Results

An increased effect of the intervention on mental distress and subjective well-being was found in students with higher scores on neuroticism. Students with higher scores on conscientiousness showed an increased effect of mindfulness on study stress. The training appeared to protect students against the increase in mental distress and study stress and the decrease in subjective well-being seen in the control group after the intervention. Baseline mindfulness and extroversion did not moderate the effect of the intervention on the outcomes.

Conclusion

Mindfulness training had greater effects on students with higher scores on the personality traits of neuroticism and conscientiousness. The majority of these students were female. We noted an increase in mental distress and study stress and a decrease in well-being in the control group compared to the intervention group.

Additional results

Hopkins Symptom Checklist (SCL)

The baseline scores for mental distress in our student sample were high. The mean baseline value on the SCL in our sample was 2.2, while the Norwegian population mean for the 16-24 age group is 1.73* (97) (*The

population mean SCL value was based on a 4-point Likert scale – we therefore recalculated this value for a 5-point Likert scale, as used in our study.) The pre-intervention value and SD values in both the MBSR and control group were 2.2 (0.9), and the post-intervention values were 1.9 (0.6) and 2.3 (0.9) respectively. The between-group Hedges' g effect size was therefore 0.41 (95% CI = .18, .64).

Empathy

The baseline empathy mean score and SD values measured using the JSE-HP questionnaire were 115.6 (10.6). This compares favourably with the findings of a JSE-S study of 456 first year American medical students which reported a mean score of 115.1 (10.0) (112). No significant differences were found between the empathy scores of the medical and psychology students. The mean values for empathy before and after the intervention remained virtually unchanged in the intervention and control groups, and the between-group Hedges' g effect size was 0.05 (95% CI = -.18, .24).

Coping

Table 1 shows the mean score and SD values, and the between-group Hedges' g effect sizes for three dimensions of coping (problem solving, seeking social support, and avoidance based). The results below will be included in a new article on mindfulness, coping and personality that is currently being drafted.

Table 1. Mean and SD values for three dimensions of coping

	Intervention *N*=144		Control *N*=144		
	Pre *M (SD)*	Post *M (SD)*	Pre *M (SD)*	Post *M(SD)*	Between group Hedges´ g (95% CI)
Problem-focused	34.56 (6.04)	36.34 (6.08)	35.60 (6.39)	35.66 (6.35)	0.28 (.05, .51)
Seeking social support	21.65 (6.07)	22.99 (5.84)	22.28 (5.80)	22.58 (5.76)	0.18 (-.05, .41)
Avoidance-based	32.76 (9.66)	30.60 (9.92)	31.78 (9.15)	31.30 (9.57)	0.17 (-.06, .40)

Note: CI = Confidence Interval, based on pooled post-intervention SD.

Social support and life events

The scores for social support at baseline were negatively correlated on the GHQ, SCL, MBI-S and PMSS measures, and positively correlated on the SWB measure at baseline (all the correlation coefficient values were between 0.3 and 0.4). The values remained virtually unchanged after the intervention. The degree of social support at baseline did not predict the

effect of the intervention on any of the outcomes, nor did the degree of social support moderate the effect of the intervention on any of the outcomes.

No significant correlations were found between negative life events or positive life events and any of the outcomes either at pre-intervention or post-intervention. One hundred and twenty-nine students reported that they had experienced one negative life event in the last year, while 51 students reported experiencing a positive life event. Treating negative and positive life events as fixed factors in a MANCOVA analysis showed that neither positive or negative life events had a significant effect on the outcome measures at post-intervention (using the baseline values of the outcomes as covariates), and they did not moderate the effect of the intervention on any of the outcome measures.

Discussion

This section will first examine the three key research questions related to this thesis (please also see 'Research aims and questions'), before briefly discussing additional study findings presented in the results section that was not published in Paper II. Finally, the section explores the implications of our study results for the delivery of MBSR interventions in higher education and presents suggestions for future research.

The effectiveness of MBSR interventions in improving health, quality of life, and social functioning in adults and in students

Our meta-analysis of MBSR interventions included data from 26 studies and showed a consistent and moderately large effect on outcome measures of stress, anxiety, depression, and on a combined mental health outcome. The heterogeneity of the studies was found to be low. The strength of the evidence was high for the combined mental health outcome and the stress outcome but found to be moderate for the outcomes of anxiety and depression. According to the GRADE system for evaluating the strength of evidence, this implies that further research is unlikely to change our confidence in the estimate of effect of MBSR interventions for mixed clinical and non-clinical populations. The meta-analysis included only four studies of student (medical) populations (38, 39, 43, 135). In addition, one further study of undergraduate students was included in the review but these data could not be used in the meta-analysis (136). MBSR versus control group data from this trial has since been published (137), and shows a between-group Hedges' g effect size of 0.5 on reducing stress, and a Hedges' g effect value of 0.3 on increasing subjective well-being at one year following the intervention. The combined mental health Hedges' g effect size in the five studies of student populations varied from 0.40 to 1.81 after the intervention, although the strength of this evidence may be limited given the

low overall number of participants (N=189). Updated searches conducted after the publication of our meta-analyses have identified no new RCTs of MBSR interventions for students. Only one published controlled non-RCT study of 52 psychology students has subsequently been identified in which treatment as usual was given to a control group (138). The results for measures of mental health outcomes were similar to our own study.

Since the completion of our meta-analysis, several other reviews focusing on the effects of stress interventions for students have been published. A recent review and meta-analysis of interventions to reduce stress in university students (12), for example, found 29 randomised and parallel cohort quasi-experimental studies. The criteria included any type of psychological, psycho-educational and/or psychosocial interventions. The 29 studies originated collectively across four continents and different university courses, and 72% of the participants were women. The primary outcomes were psychological stress and anxiety symptoms measured by the State-Trait Anxiety Inventory (STAI) and the Perceived Stress Scale (PSS). The secondary outcomes were depression (measured using Beck's Depression Inventory) and levels of salivary cortisol. Twenty-four of the interventions were cognitive/behavioural/or mindfulness-based, two were arts-based, two classified as psycho-educational, and one intervention was healing/energy-based. Only data from the cognitive/behavioural/or mindfulness-based interventions could be used in the meta-analysis, and included a total

sample of 1,431 students. In this group, seven studies were mindfulness-based trials, and 11 studies used a combination of relaxation training and cognitive/behavioural techniques. The cognitive/behavioural and mindfulness-based interventions were associated with decreased symptoms of anxiety after the intervention (Hedges' g = 0.73, CI = .59, .89), and lower levels of depression (Hedges' g = 0.81, CI = .13, 1.49) and cortisol (Hedges' g = 0.52, CI = .2, .84). The mindfulness-based interventions had the same effect on anxiety as the cognitive/behavioural interventions. However, most of the study sample sizes were small (the largest was N=81), and no large randomised controlled trials were found which used mindfulness-based interventions.

Another recent systematic review of stress-management programmes for medical students (139) identified 13 studies. Five were randomised controlled trials and eight were controlled non-randomised trials. The interventions included a variety of health promotion programmes, including self-development groups, yoga, mindfulness training, self-hypnosis, group stress-management, time stress-management, reflective writing, curriculum changes, grading changes and educational electives. MBSR programmes, meditation courses, self-hypnosis courses and pass/fail grading interventions showed significant effects on stress and anxiety.

We have identified subsequently a general meta-analysis of mindfulness training which did not focus specifically on students (140). The

analysis included both RCTs and non-controlled pre-post studies of mindfulness programmes that were not combined with other treatment methods. The study calculated a combined Hedges' g treatment effect value based on all the physical and psychological outcome measures for each of the studies. In addition, a separate effect size was calculated based only on measures of mindfulness. The majority of the outcome measures were psychological measures of stress, anxiety and depression. Two hundred and nine studies (109 RCTs) – with 12,145 participants – were included. The mean Hedges' g treatment effect value for the 44 included pre-post MBSR studies was 0.57 (CI = .50, .64) for the combined outcome. The mean effect size for the 38 wait-list controlled MBSR studies was 0.52 (CI = .42, .62). The findings were very similar to those from our meta-analysis, and confirmed the validity of our findings. Thirty-five studies comparing mindfulness training to other active interventions were also included. A mean effect size of 0.33 (CI = .26, .41) was reported for the mindfulness training. The effect of mindfulness training did not differ, however, from cognitive based therapies, behavioural therapies or pharmacological treatments.

In conclusion, the meta-analysis we conducted of 26 studies with both clinical and non-clinical populations found consistent evidence showing that MBSR interventions have a moderate effect on a combined mental

health outcome. This finding has been further supported by a subsequent comprehensive meta-analysis of mindfulness training (140).

Did our two-centre RCT show that MBSR training enhances mental health among medical and psychology students?

Our two-centre RCT study reported an overall Hedges' g effect size on a single, combined mental health outcome of 0.36 (0.65 for mental distress measured using a GHQ; 0.40 for mental distress measured using the SCL; 0.41 for subjective well-being; 0.17 for student stress; and 0.15 for burnout). The results related to mental distress and well-being are consistent with other MBSR studies of students and with the results of our meta-analysis.

The effects on student stress and burnout in our study were lower than the levels reported in other studies. One reason for this may be due to the floor effect of the very low baseline levels recorded. Scores for the stress levels among the second year students were significantly lower ($p<.0001$) than those reported in a controlled study of 281 third year medical students at another Norwegian university in 2002, which used a PMSS scale to measure the effect of self-development groups on reported stress (107). Several studies have indicated that stress levels reported by medical students increase over the course of their studies. The lower levels of

reported stress among the second year students in our study are therefore not necessarily unexpected (141, 142).

The small between-group effects on stress noted in our study may also have been due to the increase in reported stress levels by the male students in the intervention group after the intervention. This rise in reported stress may have been caused by an increase in their awareness of stress following the completion of the mindfulness training. Alternatively, the rise may represent a regression to the mean, given that the pre-intervention stress levels were initially very low. Since the male students in the control group (who also reported low levels of stress before the intervention) did not report a similar increase in stress, it is more likely that the first explanation is correct. It is possible too that the PMSS measure itself was not sensitive to change, but in light of findings from previous PMSS intervention research (107), this explanation is unlikely.

The lack of effect on burnout might be explained in similar ways. The baseline levels of burnout in the students in our study were similar to those recorded in a study of Spanish undergraduate medical students, who were later found to have significantly higher levels of burnout when re-examined in their final study year (143). The hypothesis that mindfulness training could prevent an expected increase in burnout as students progressed further in their studies informed part of the power calculation used in our RCT trial. Future follow-up data will help us to assess this proposed

hypothesis. It is also worth noting that the Norwegian version of the MBI-S has not been formally validated for Norwegian student samples. Findings using this measure may, at this stage, be less reliable. A principal component analysis based on our student sample did however show satisfactory results (Appendix 4). In addition, the variations related to mental distress and burnout supported the notion that these represent distinct concepts.

In conclusion, the effects of our intervention on mental distress and well-being were as we anticipated. The effects on study stress and burnout, however, were lower than expected and may have been due to the floor effect of the very low baseline levels.

Are intervention effects influenced by individual factors (gender, mindfulness practice, personality and baseline mindfulness), and organisational factors (university, course, class, or instructor)?

Surprisingly, our RCT trial showed that only female students benefited significantly from the intervention, and this issue is discussed in more detail in Paper II. In a recently-published large meta-analysis of mindfulness-based interventions (140), gender was examined as a predictor of effect. Most of these studied older populations and reported no gender effect. Previous MBSR studies of students did not examine gender effects, while a

review of mindfulness based interventions in treatment of substance abuse did find some evidence supporting a greater effect for female participants (144).

One possible explanation for the difference noted in our study could be that the mindfulness training may have had a different effect on male and female students because they were at different stages in their personal development. It should be noted, too, that the male students scored significantly lower on neuroticism and conscientiousness and this may therefore have accounted for the variance in effect based on gender. It may also be that male students need a different kind of mindfulness training, or a different way to introduce and teach mindfulness.

In our study, a higher percentage of female students signed up for the study, and in Norway a large majority of the participants on mindfulness courses are usually women. When I attended courses at the Center for Mindfulness in Massachusetts the gender distribution was, in contrast, nearly equal. I noticed that more action-oriented language was used at the Center when discussing mindfulness; staff spoke, for example, of the need to train the 'muscle' of attention. In our study, the words we used were more feeling oriented. In the mindfulness training currently being tested on fighter pilots in Norway, the instructors have referred far more to the importance of mental training in relation to performance. Further exploration should

therefore be undertaken to examine the effects of contextualising mindfulness training for male students.

A floor effect caused by the lower baseline scores of the male students on stress and mental distress may also explain the lower between-group effect sizes. However, the fact that the female students reported a far larger increase in subjective well-being compared to the male students, despite the baseline scores being nearly equal, indicates that the effects of the intervention may be influenced by gender differences (Paper II). The low number of male students that received the intervention, it could be argued, may have weakened the strength of our findings, and further studies will be needed to clarify potential gender effects more precisely in student populations.

Levels of attendance and home practice were nearly equivalent for men and women, but while both attendance and reported home practice were predictors of effect on mental distress, they were not predictors of effect on study stress or subjective well-being. Findings about the relationship between compliance and outcomes in mindfulness studies have been contradictory. A large published meta-analysis of different mindfulness-based programmes (140) reported that the combined clinical outcome was positively moderated by the duration of the programme but not by duration of assigned home practice. The effect size, however, was strongly positively correlated to the effect size on the mindfulness outcomes. The authors of the

meta-analysis thus suggested that better process measures were needed to assess whether participants *were* actually practising mindfulness training when attending mindfulness courses.

The personality factors of neuroticism and conscientiousness were both found to be moderators of the effect of mindfulness training. Both factors have been found to predict future medical school stress (78) and neuroticism has been shown to be the personality trait with the strongest correlation to mental disorders (145). The effect of the intervention when analysed using multiple regression tests remained significant even after controlling for baseline levels of these two personality traits. Evidence suggests that when mindfulness-based interventions are used to prevent mental problems, it is especially effective for vulnerable people, while. those with a low level of mental health vulnerability have been shown to experience the same effect when receiving the group process without the mindfulness training (146). Vulnerability may enable participants who receive mindfulness interventions as prevention to remain in contact with their own stress/distress. This may make it easier for them to learn how not to avoid it (and thereby to manage it more effectively) and not to become entangled in ruminations. Our study showed that those scoring high on neuroticism and conscientiousness in the control group reported increased levels of stress/distress at post-intervention. This suggests that vulnerability may be a useful selection

criterion when choosing which students should be offered the MBSR intervention.

The effects of the intervention were shown to be independent of the study course, curriculum, university, or particular course instructors. Although this increases the generalisability of the results, it remains to be seen whether this association will remain consistent at follow-up after two, four, and six years. The high percentage intake of students directly from high school, and the high entrance requirements to the courses at both the universities in our study, we contend, makes the study populations and settings very similar. It is highly probable that future findings of effects will not vary substantially over time across classes, curricula, or between universities. As noted earlier, all the instructors involved in our study were qualified mindfulness teachers and had practised mindfulness for many years. The fact that the use of different instructors did not impact on the student experiences is therefore not surprising. It should be noted, however, that a recent meta-analysis (140) has shown that having an instructor with experience in mindfulness training can influence the effect of an intervention.

Discussion of additional results

The short version of the Hopkins Symptom Checklist is regarded as a suitable screening instrument for mental distress targeting symptoms of

anxiety and depression (96). A somewhat smaller effect size was recorded on the Hopkins SCL compared to the GHQ measure. In the GHQ, respondents are asked whether their symptoms are more or less prevalent compared to what they were two weeks ago. As such, the questionnaire focuses on interruptions in normal functioning. In contrast, the SCL asks respondents to grade the degree to which they are experiencing different symptoms. The fact that similar results were recorded across two different mental distress measures strengthens our confidence in the effect of the intervention on mental distress. Both measures were highly correlated at baseline, indicating that they are both measures of the same underlying construct.

We hypothesised that the mindfulness intervention would have an effect on the coping style of the students (90). The increase we observed in engagement coping, and the decrease in avoidance based coping, supported this. Both findings were in line with other research findings within this field (147, 148). Future analyses of the data from this trial will explore the effects of the intervention on coping styles and the moderating effect of personality.

Our study showed that the mindfulness intervention had no short-term effect on empathy. This finding contrasts with an MBSR study of pre-medical and medical students (39) which found a significant effect on empathy at post-intervention. Several possible reasons may account for this difference:

firstly, the other study used a different measure of empathy (the Empathy Construct Rating Scale). Secondly, the intervention was offered as an enrichment elective and was eligible for study credits. Thirdly, each of the seven sessions were longer and lasted 2.5 hours, compared to our shorter 1.5 hour-long sessions. Fourthly, compliance in the MBSR study may have been higher because students were required to log their practice daily and to hand in the records every week. It is also worth noting that most of the between-group effects found in the MBSR study were due to the worsening of empathy in the control group when measured after the intervention close to the end-of-term exam. In contrast, a pre-post study of mindfulness training (138), which also used the Jefferson Empathy Scale, did not find a significant change in empathy post-intervention. Participant empathy, we hypothesised, would change over a longer follow-up period, both in the control and intervention groups. This claim will be assessed when data from the two and four-year follow-up are analysed.

Higher levels of perceived social support were positively correlated with well-being and negatively correlated with measures of mental distress, as we expected based on evaluation of other studies of medical students and doctors (18, 149). But social support at baseline was not found to predict or moderate the effect of the intervention on any of the outcome measures. It is therefore likely that the intervention effect is independent of the degree of social support reported.

The occurrence of negative life events during the course of the last year was not correlated with the outcome measures. In contrast, a multi-centre study of medical students found that negative life events (personal/family illness, death of a family member, or divorce) in the prior year were associated with an increased risk of burnout (26). One possible reason for this discrepancy could be that the multi-centre study included more questions about negative life events, including a separate question about the 'death of a family member'. Loss, as has been shown, is a prominent element of negative life events (150). Other reasons for the discrepancy could be that the age of the other sample was higher (the study included students from all study years).

Positive life events may also influence mental health and well-being. In our study though, no correlation was found with any such outcome measures at baseline or post-intervention. The students were asked only about getting married or having a child, and given the age of the participants, few had experienced such events in the preceding year.

The suitability and delivery of the MBSR to student populations

The majority of the students in our study attended most of the mindfulness classes and the low attrition rate is an indication of their relevance to the students. Similarly, 98% of medical students participants who took part in another mindfulness course stated that they would

recommend it to other medical students (42). The very high level of support for our course may be explained by the fact that: firstly, the MBSR course addressed the issue of how to handle stress – a topic of direct relevance to a large proportion of the students. Secondly, the course taught a broad set of formal and informal techniques which could be readily applied to the challenges faced in the course of a typical student day. Thirdly, the training provided a supportive group experience in which the students could share and learn from each other and strengthen relationships with their fellow students. Fourthly, the attention training which teaches participants how to sustain their attention and concentrate on what they are doing in the present moment is highly relevant to students in a university environment. Finally, it is likely that the students readily understood the importance and benefits of fostering attitudes of acceptance and tolerance towards their own thoughts and feelings. Medical students, as noted earlier, are often highly ambitious and self-critical and may have perceived such skills as self-advantageous. While it may not be possible to determine exactly the motivations of the students, the insight and learning offered by the MBSR were evidently relevant to those studying in the helping professions. The fostering of mindfulness, as a therapist and senior researcher in this field has argued, should be considered a core component of good clinical practice (151).

Compliance with the home practice exercises fell far below the recommended levels of the programme (Paper II). Both attendance and the home exercises are important to shaping the outcomes of the MBSR training. How interventions should be designed to ensure that students practise more regularly is an area of concern. At present, few examples are available of MBSR interventions delivered to medical or psychology students as part of their curriculum. At Monash University in Australia, the central elements of the MBSR course have been incorporated into the core undergraduate medical curriculum (152). The purpose of doing so is to foster student well-being and to enhance holistic medical education. By the end of the mindfulness programme, 90% of the students reported practising mindfulness at least once a week (152). The pre-post Cohen's *d* effect size for mental distress (General Symptom Index from the SCL-90) was small (0.27) and only data related to 148 of the total 270 eligible student cohort were measured. We cannot therefore conclude that an obligatory mindfulness course will yield better results or higher compliance levels than those reported in our trial.

At the Boston University School of Medicine, training is offered via an elective course which consists of a component in which students learn about yoga and mindfulness techniques, and a second component in which students learn about neuroscience. In a pre-post study of 27 students (138), the combined Cohen's *d* effect size on mental health measures was found to

be 0.28 (the average effect size for stress, self-regulation, empathy and self-compassion outcomes measures).

Other techniques of administering mindfulness training have also been tested. In a recent well-designed and well-executed RCT, the mindfulness intervention included only an audio CD with guided mindfulness practices which lasted 30 minutes and was practiced daily for eight weeks. (153). The authors found significant and clinically meaningful reductions in stress after the intervention and at eight weeks follow-up. Only 24 of the 32 participants in the mindfulness group were assessed at post-intervention, and the participants practised mindfulness on only 27 of the recommended 56 days. Despite these limitations, this study was the *only* stress management programme for medical students that received a full score on the validity scale in a recent systematic review (139).

As yet, we therefore do not have sufficient knowledge to determine the most effective way to deliver mindfulness training in ways that are certain to maximise the positive effects for students.

Implications for higher education

Evidence supporting the integration of mindfulness meditation into higher education has been reviewed in a recent study (154). The results indicated that doing so can be beneficial and can improve student attention,

information processing, and academic performance. Since the publication of this review, further studies have reported similarly favourable results (155).

Academic stress/distress may negatively affect memory and academic performance. Mindfulness, as research has increasingly shown, has positive effects on academic stress/distress, and the results from our study related to this issue – discussed in Papers I to III – found similarly positive benefits.

Incorporating mindfulness meditation into higher education is important given that mindfulness has been shown to have potentially beneficial effects on human development, including interpersonal functioning, emotional balance and empathy. As Shapiro et al (p. 509) suggest (154), integrating mindfulness meditation into higher education may contribute to building "greater capacity for positive interpersonal behaviour and healthy social relationships". Follow-up analyses from our trial will hopefully provide further evidence of the validity of this claim.

Growing evidence suggests that the effects of introducing mindfulness training into higher education will be beneficial. Many of the studies undertaken thus far have suffered from methodological limitations and firm recommendations at this stage are therefore inappropriate. The potential benefits identified thus far, does however, indicate that further investigation is warranted.

Recommendations for future research

Based on the available evidence and the results of our RCT, we would suggest that study design changes are needed in order to improve the quality of research in this field and to ensure progress. First, it would be wise to stratify for gender in the randomisation process, and to ensure that enough male students are included in study samples. This will make it possible to assess the effects of the intervention on men. Second, steps should be taken to ensure better compliance. Analysing how compliance affects intervention outcomes will also be important. Better use of available technologies, such as smart phone apps, could enable researchers to monitor home practice. Third, to assess differences in effects, different lengths and forms of mindfulness training should be tested and compared in the same study. An intervention sample, for example, could be split: half the students could be provided with a mindfulness app which provides short, guided mindfulness exercises at regular, set intervals, while the other half could attend a mindfulness course. Other possible intervention structures could include e-learning modules (short didactic teachings, for instance, delivered together with guided exercises) versus more traditional course formats. Students could post questions to the teacher online and receive feedback about their practice in a similar way. Such comparisons could help us to understand better the key essential elements of more effective mindfulness programmes. Fourth, the effects of compliance need to be tested more rigorously. This could be achieved by testing the students in a

laboratory setting halfway through an intervention period. Close attention should be given to an assessment of student attention skills and emotion regulation skills, and the same measurement assessments could be repeated again at the end of the programme. Such process monitoring could facilitate analysis of mediators of the intervention effects. Fifth, self-reported outcome measures should be supplemented by physiological measurements, such as heart-rate variability, that can indicate a person's ability to manage stress (156). Immune markers responsive to stress levels could also be measured (the use of meditation or exercise has been studied, for example, as a way of preventing acute respiratory infection) (65). Longer follow-up periods are needed, too, when assessing potential long-term effects, including completion rates and exam results in student populations, where relevant. Finally, the effects of mindfulness on professional performance and patient satisfaction after graduation should also be evaluated. In our study, the follow-ups will continue until one year after the students have qualified. This will allow us, hopefully, to answer some of these important questions.

Conclusions

Medical and psychology students experience substantial stress that may have serious potential consequences for their future health and professional lives. Teaching students skills that will help them to increase their ability to manage stress and promote their personal development is therefore important. This thesis reviewed the evidence base on the effects of

MBSR interventions and showed that there is consistent evidence for a moderate effect of MBSR programmes on stress and a combined mental health measure in adults, and an indication of a positive effect on student populations. Further, our RCT demonstrated that the mindfulness intervention had a moderate effect of on the mental distress of female students. We also found a small effect on study stress, well-being and mindfulness. In addition, our trial showed that the mindfulness training led to an increase in active problem-based coping. Students with high scores on the personality traits of neuroticism and conscientiousness benefitted more from the intervention: the intervention protected them against the increased mental distress and study stress reported by students in the control group. Universities should encourage further trials on intervention programmes to promote student well-being and personal development, and to increase student stress-management skills. Such programmes should focus particularly on the training of the mind in addition to the training of the body, and emphasise the importance of a balanced, healthy lifestyle. Mindfulness training is a promising intervention that could help, ultimately, to enhance the quality of professional training and care. As such, mindfulness interventions should be given greater research attention within educational settings.

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Appendices

Appendix 1. Invitation letter to participate in the study

Invitation to participate in the study: Mindfulness training and stress management for 2nd term medical and 3rd term psychology students

We are pleased to invite you to participate in a research study in which we will examine if a method for stress management can reduce stress and promote the personal development of medicine and psychology students.

Good patient care depends on healthcare professionals who have developed strong abilities to see, understand and communicate with patients, in addition to coping with stress that the study and the job entails. Several studies show that students and health professionals struggle with significant stress, psychological distress and low quality of life, and the problems remain for at least 10 years after qualifying.

The method we will use has been tested in experiments with students in the USA and has been shown to reduce stress and psychological distress, and increase well-being and the ability to empathise and be present.

The participants who sign up will randomly be invited to attend the course in stress management or join the control group who continue the study as usual. The course starts in the 2nd week in September and has six weekly evening sessions of 1.5 hour each, in addition to a one-day session of six hours in week seven. Participants will receive teachings on basic

physical and mental exercises that promote personal development and stress management. Between sessions the participants practice home exercises 30 minutes daily. Course materials are free. Throughout the remainder of the study, those who have attended the course will be offered a 1.5-hour follow-up session each term. Those who participate in the control group will be offered a similar course free of charge, after the study is completed. Participants will get paid for filling out questionnaires in the form of a book voucher from the university bookstore.

We hope that you would like to participate. Visit the website www.kunnskapssenteret.no/OT. There you will find information about the study, and you can register and fill out the consent form and questionnaire. The deadline for registration and completion of the questionnaire is ..... If you have any questions, feel free to call or send me an email.

Very best regards

Michael de Vibe

Project Manager for the study

Norwegian Knowledge Centre for the Health Services

mfd@kunnskapssenteret.no

Tel: 91610957

Appendix 2. Approval from the Regional Committee for Medical and Health Research Ethics, Faculty of Medicine, University of Oslo, Norway

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DET MEDISINSKE FAKULTET

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Nettadresse: http://helseforskning.etikkom.no

Dato: 29.06.09
Deres ref.:
Vår ref.: S-09268c 2009/5781 (oppgis ved henvendelse)

Vedr. oppmerksomhetstrening for å mestre stress: En randomisert to-senter studie for medisin- og psykologistudenter

Vi viser til brev med svar på komiteens merknader til ovennevnte prosjekt av 05.06.09. Justert versjon av protokoll var vedlagt brevet.

Prosjektet ble godkjent i møte 22.04.09. Komiteen tar brevet med innhold til orientering.

Det gjøres oppmerksom på at REK har lagt om til elektronisk saksbehandling fra 04.05.09. All korrespondanse skal fra denne datoen gå via saksportalen: http://helseforskning.etikkom.no

Med vennlig hilsen

Arvid Heiberg (sign.)
professor dr. med.
leder

Tor Even Svanes
komitésekretær

Kopi: Den norsk legeforenings kvalitetsfond, v/ Anne Sofie Torp, Postboks 1152 Sentrum, 0107 Oslo

Appendix 3. Description of the MBSR programme

Class One: Mindfulness and the power of being present. Introduction to what it means to be mindful on a theoretical level, through didactic teaching. In an experiential "raisin exercise", participants were then asked to eat a raisin slowly while trying to stay present in each facet of the sensory experience. Physical anchoring exercises and a body-scan exercise were also introduced to participants. During the body-scan exercise, attention was given to each part of the body. Participants were asked to notice only what sensations arise while doing this. The focus of the class was on the causes and consequences of having an absent mind, and the benefits of being fully present to what is happening in the present moment. An important distinction was made between seeing thoughts as facts and being aware of thoughts as objects that can be observed. The home practice consisted of: a 15-minute body-scan exercise (from a CD with mindfulness exercises developed by the PhD candidate) once a day for six days, and one selected daily activity that participants had to undertake in a state of full awareness every day in the coming week. Suggestions for mindfully-performed daily activities were given in the workbook and included hand washing, stopping in the traffic at a red light, taking a shower, eating dinner, answering the telephone, and getting dressed.

Class Two: Perception – how we perceive reality. In the second class, the students participated in a guided sitting meditation session which

focussed on breathing. The theme of the class was how perceptual processes shape experience. Participants were introduced to information about how experiences and expectations earlier in life shape perception. Mindfulness, it was noted, makes new interpretations and actions possible because it is a mode of perception that is both curious and open, one that welcomes reality just as it is, without analysing or judging what arises. The home practice assigned for the following week was a daily 15-minute body-scan practice for six days and a sitting meditation practice of between 5-15 minutes daily. This latter task was designed to bring a person's attention gently back to the breath each time they discover that their attention had moved away from the breath. Participants were asked to choose a new activity that they would perform mindfully each day. Additionally, participants were asked to notice one pleasant event each day in the coming week and to note any sensations, thoughts and feelings associated with the event.

Class Three: Stress and how it affects us. Two new formal mindfulness exercises were practised in Class Three, as well as slow stretching exercises from the hatha yoga tradition. These tasks were performed with full attention given to sensing the body rather than doing the exercises correctly. During a walking meditation session, the students were asked to walk slowly in a circle and to rest their attention on the contact between the feet and the ground, and to bring their attention gently back to their feet each time the attention 'wandered off'. The class was centred on the concept

of stress, and how stress is manifested in the mind and body. The home practice assignments for Week 3 were: to alternate for six days between doing 30-minute yoga stretching exercises when lying down and the body-scan exercise. Participants were also asked to practice sitting meditation for 5-15 minutes every day. They were also asked to notice unpleasant events and to take note of the sensations, thoughts and feelings associated with these events.

Class Four: Coping with stress. Standing yoga stretching exercises, sitting meditation, and walking meditation were practised during Class Four. The theme of the class was how the capacity to be aware of the mind and body in stressful situations – without immediately reacting to either – makes it possible to adapt more effectively to challenges and stressors. The breath was highlighted as an important place to anchor one's awareness when feeling stressed. In the following week, the participants were invited to alternate daily for six days between 15 minutes of sitting meditation *and* 15 minutes body-scan *or* exercises in hatha yoga. As part of their home practice, participants were asked to pay attention to their breathing both in everyday situations, especially stressful ones, and to open up to new ways of responding to stressful situations.

Class Five: Communication. Class Five consisted of sitting and walking meditation and hatha yoga exercises. The emphasis of the class was on interpersonal mindfulness. Interpersonal reaction patterns and habits of

emotional expression/suppression were discussed. Mindfulness was highlighted in this context as the capacity to stay aware of one's own experiences, including thoughts and interpretations, emotions, and behavioural impulses during communication. In Classes Five and Six, participants were asked to do one formal mindfulness practice every day. The choice was either a body-scan, sitting meditation and hatha yoga, or experimenting with the exercises without listening to the CD instructions. The participants were also invited to pay close attention to how they communicated with others in the following week, and to accept their own reactions without necessarily trying to change anything. Finally, the students were asked to select one activity that they would do with full awareness each day.

Class Six: Self-reliance. Class Six consisted of guided practice in sitting and walking meditation. The focus of this class was on acceptance and trust in oneself and in life. The difficulties of accepting oneself and forgiving oneself and others were discussed. Participants were asked to do the same formal exercises as in Week 5. In addition, they were invited to experiment with trust, openness and acceptance towards themselves, others, and life in general.

Class Seven: A six-hour mindfulness session. The participants were invited to practice mindfulness for a whole day, in silence, in Week 7. Instructions in different formal practices were given including anchoring,

meditation focusing on sensory impulses such as sounds, the breath, on thoughts and emotions arising, and finally on practising being aware to whatever arises in one's consciousness. Standing and lying yoga exercises were also done. During the day, a meal was eaten in silence, followed by a 30-minute walk, also without conversation. In the last 45 minutes of the day, the group reflected on how people had experienced the silent day and provided informal feedback on the programme as a whole.

Appendix 4. Principal component analysis of the MBI-S

Prior to conducting the factor analysis assessment, the suitability of the data was evaluated. The sample size adequacy was assessed using the Kaiser-Meyer-Oklin (KMO) test. A KMO value of .889 was found: this exceeded the recommended value of .6 (157). All the KMO values for individual items were >.850, and above the recommended limit of .5 (157). A Bartlett's test of sphericity showed a significance of $p<.001$ – a level which confirmed the factorability of the correlation matrix. An initial analysis was run to obtain eigenvalues for each data component. A Principal Component Analysis (PCA) revealed the presence of three components with eigenvalues which exceeded 1.

This accepted solution was identical to the solution for the original MBI-S. When extracting three factors using oblimin rotation, the five items that constituted the "exhaustion" subscale in the original version showed the strongest loading on Component 1. The four items that constituted the "cynicism" subscale showed the strongest loading on Component 3, while the six items from the "study efficacy" subscale were most strongly loaded on Component 2.

All the KMO values for the individual items were found to be >.690, a level well above the recommended value of .5. All items loaded strongly on

one subscale only. The correlation coefficients between the three subscales were between .326 and .406. The Cronbach's alpha for the subscales were .87 for exhaustion, .86 for cynicism, and .85 for study efficacy, and .90 for the burnout sum scale used in our analysis.

Appendix 5. Translation procedure for the Jefferson Empathy Scale (JSE)

The translation of the JSE scale occurred in four stages. First, the PhD candidate who conducted the mindfulness training at the University of Oslo, and a Norwegian professor in psychology with a PhD in empathy, separately translated the scale from English into Norwegian, then discussed and agreed upon the wording of the Norwegian version.

Second, two native English speaking, bilingual colleagues at the Norwegian Knowledge Centre for the Health Services, who had not seen the original English version, separately back translated the Norwegian version into English, and then discussed and agreed upon the final wording of the English version. Third, all the translators met and compared the original English version with the back-translated English version and agreed on how to correct the inconsistencies. Fourth, wording adaptations were made by the two Norwegians to some of the items. These changes made the text consistent within a Norwegian cultural setting, but care was taken at the same time not to lose the intended meaning of the key concepts.

Fifth, the Norwegian team did a pilot test of the questionnaire on 20 master's degree students in mental health (nurses), and asked them to comment on any questions that they did not fully understand. After final adjustments, the questionnaire was tested on four different student classes with a total of 138 students. The sample included: 1. Master's students in mental health work (nurses, occupational therapists, physiotherapists),

2. Nurses specialising in operation nursing, 3. Intensive care nurses, and 4. A sample of fourth year medical students. The scale performed as expected with women scoring higher than men, and nurses in mental health scoring higher than nurses specialising in operation or intensive care. The Cronbach's alpha for the sum scale in our test population was .81, and in our student sample was .78.

Appendix 6. Principal component analysis of the WCCL

Prior to conducting the factor analysis assessment, the suitability of the data was evaluated. Sample size adequacy was assessed using the Kaiser-Meyer-Oklin (KMO) test. A KMO value of .828, was found: this exceeded the recommended value of .6 (157). All KMO values for individual items were >.503, and were just above the recommended limit of .5 (157). A Bartlett's test of sphericity showed a significance of $p<.001$ – a level which confirmed the factorability of the correlation matrix. An initial analysis was run to obtain eigenvalues for each data component. A Principal Component Analysis (PCA) revealed the presence of twelve components with eigenvalues exceeding 1.

This accepted solution was dropped because several components had only 1 item with strong factor loading. The scree-plot was then examined as a criterion for factor extraction. The scree-plot showed inflexions that justified the retention of 3 components.

When extracting the 3 factors using an oblimin rotation, items that constituted the "problem focused coping" subscale in the original WCCL loaded most strongly on Component 1. Items that constituted the three subscales of the WCCL relevant to an avoidant style of coping (blame self, wishful thinking, and avoidance) had the strongest loading on Component 2. Items from the "seek social support" subscale of the WCCL loaded most strongly on Component 3. Three items from the avoidance subscales (item

numbers 12, 35 and 38) relating to the avoidance of social contact or hiding ones feelings from others, were also loaded on Component 3. These items were consequently included as part of the underlying construct represented by Component 3 in further analysis, and the scoring was reversed. Item 18 ('Accepted the next best thing to what I wanted') from the problem-focused coping scale was deleted because of the low factor loadings calculated (<.04). Item 27 ('Got mad at the people or things that caused the problem'), originally an item in the avoidance subscale, had a low and almost equal factor loading on all three components (.2-.3). Consequently, this item was not included in further analysis. The PCA was rerun after deleting item numbers 18 and 27. KMO analysis (KMO=.834) and a Bartlett test of sphericity ($p<.001$) confirmed that the data were still suitable for factor analysis. All KMO values for individual items were >.624. All three components showed a number of strong loadings and most of the variables loaded substantially on only one component. According to Field (157), a factor solution is stable if each factor has 10 or more loadings greater than 0.4 in a sample that exceeds 150. The three component factor solution for the WCCL for this sample came very close to fulfilling this criterion as Components 1, 2 and 3 had 10/13, 14/17 and 8/9 factor loadings above .4, respectively. The correlations between the factors were .210 (1 and 3), .077 (1 and 2) and .199 (2 and 3).

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Campbell Systematic Reviews
2012:3
First published: 01 February, 2012
Last updated: 11 January, 2012
Search executed: 21 September, 2010

Mindfulness Based Stress Reduction (MBSR) for Improving Health, Quality of Life, and Social Functioning in Adults

Michael de Vibe, Arild Bjørndal, Elizabeth Tipton, Karianne Hammerstrøm, Krystyna Kowalski

THE CAMPBELL COLLABORATION

Colophon

Title	Mindfulness based stress reduction (MBSR) for improving health, quality of life, and social functioning in adults.
Institution	The Campbell Collaboration
Authors	de Vibe, Michael Bjørndal, Arild Tipton, Elizabeth Hammerstrøm, Karianne Thune Kowalski, Krystyna
DOI	10.4073/csr.2012.3
No. of pages	127
Last updated	January 2012
Citation	de Vibe M, Bjørndal A, Tipton E, Hammerstrøm KT, Kowalski K. Mindfulness based stress reduction (MBSR) for improving health, quality of life and social functioning in adults. Campbell Systematic Reviews 2012:3 DOI: 10.4073/csr.2012.3
Copyright	© de Vibe et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.
Contributions	AB proposed the topic of this review to MV. MV wrote the first draft of the protocol. KTH, a research librarian, developed the search strategies. AB wrote the methods sections of the protocol and KK designed the forms. KTH conducted the searches. MV, KTH and KK selected the studies and extracted data, and AB acted as an arbitrator when additional debate and discussion were needed. MV, ET and AB undertook the data analyses. MV and AB wrote the review. All authors have commented on different versions of this manuscript. MV will be responsible for updating this review as additional evidence accumulates and as funding becomes available.
Editors for this review	Editor: William Turner Managing editor: Krystyna Kowalski
Support/funding	This study is supported by The Norwegian Medical Association, The Norwegian Knowledge Centre for the Health Services, Centre for Child and Adolescent Mental Health, Eastern and Southern Norway, and SFI Campbell at The Danish National Centre for Social Research.
Potential conflicts of interest	MV has conducted a research project on MBSR in Norwegian family practice which was published in the Norwegian Medical Journal in 2006 and is also an MBSR instructor. MV is leading an RCT of MBSR among students from two universities; AB is his mentor. None of the authors stand to gain financially from a positive or negative evaluation of MBSR.

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Campbell Systematic Reviews

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Table of contents

Key messages

Mind-body interventions to manage stress-related health problems are of widespread interest. One of the best known methods is mindfulness-based stress reduction (MBSR), and MBSR courses are now offered by health services, as well as in social and welfare settings. In this systematic review, we report on the effects of MBSR interventions on health, quality of life, and social functioning. From the more than 3,000 potentially relevant references identified in two extensive searches, we included 31 relevant studies with an overall total of 1,942 participants, each of whom had been randomised to receive MBSR or other treatment strategies (most often a waiting list control). We utilised all outcome data published in the selected studies using a new statistical method for calculating the effect size. This method addressed the problems presented by the interdependence of many measurements of outcomes.

26 of the 31 studies were identified as having data suitable for meta-analysis. MBSR was found to have a moderate and consistent positive effect on mental health outcomes in both patients selected with somatic problems and with mild to moderate psychological problems, and among participants recruited from community settings. MBSR interventions improved outcomes measuring different aspects of personal development and quality of life. The effects on somatic health outcomes were somewhat smaller. No adverse effects were described. Few studies were found that evaluated the impact of MBSR on social functioning, such as the ability to work.

Executive summary/Abstract

BACKGROUND

Stress and distress are common experiences central to many of the problems occupying health and social services and efforts to improve both health and quality of life are receiving increasing attention. Evaluative research on mind-body interventions is also growing and one of the best studied efforts to reduce stress is mindfulness-based stress reduction (MBSR). Developed by Kabat-Zinn in 1979, MBSR is based on old spiritual traditions and includes regular meditation. Mindfulness is a way of intentionally attending to the present moment in a non-judgemental way. A number of reviews and meta-analyses on MBSR have been conducted, but few have adhered to the meta-analytic protocol stipulated by the Cochrane and Campbell collaborations. The last review of all relevant target groups was published in 2004.

OBJECTIVES

To evaluate the effect of mindfulness-based stress reduction (MBSR) on health, quality of life, and social functioning in adults.

SEARCH STRATEGY

We searched all relevant databases: MEDLINE, AMED, PsycINFO, EMBASE, Ovid Nursing Full Text Plus, the British Nursing Index and Archive, the Cochrane Central Register of Controlled Trials (CENTRAL), SIGLE, Web of Science®, SveMed+, Dissertation Abstracts International, ERIC, Social Services Abstracts, Sociological Abstracts, the International Bibliography of Social Sciences, and ProQuest. The searches were conducted in July 2008 and again in September 2010.

SELECTION CRITERIA

Randomised controlled trials on all target groups were included where the intervention followed the MBSR protocol developed by Kabat-Zinn, allowing for variations in the length of the MBSR courses. We accepted all types of control groups and no language restrictions were imposed.

DATA COLLECTION AND ANALYSIS

Two reviewers independently read the titles, retrieved the studies, and extracted data from all the included studies. We calculated standardised mean differences (expressed as Hedges' g-values) from all of the study outcomes using Comprehensive Meta Analysis. The meta-analyses were undertaken using the Metafor Package which is part of the statistical program 'R'; we used a newly developed technique (Robust Standard Errors) to address the statistical challenge presented by clusters of internally correlated effect estimates.

RESULTS

We identified 31 RCTs with an overall total of 1,942 participants. Seven studies included people with mild to moderate psychological problems, 13 studies targeted people with various somatic conditions, and 11 studies recruited people from the general population. 26 of the 31 RCTs were used for the meta-analyses (an overall total of 1,456 persons). All effect sizes are expressed using Hedges' g-values, and positive values indicate beneficial effects. Post-intervention effect sizes were as follows: for measures of anxiety 0.53 (95% CI 0.43, 0.63), for depression 0.54 (95% CI 0.35, 0.74), and for stress/distress 0.56 (95% CI 0.44, 0.67). The overall effect size post-intervention for the combined outcome 'mental health' was 0.53 (95% CI -0.43, 0.64). Heterogeneity was low and tau square-values (for between-study variance) ranged from 0 to 0.03. The results for measures of personal development were 0.50 (95% CI 0.35, 0.66), quality of life 0.57 (95% CI 0.17, 0.96), mindfulness 0.70 (95% CI 0.05, 1.34), and somatic health 0.31 (95% CI 0.10, 0.52). Results for quality of life and mindfulness showed moderate to large heterogeneity.

Effect sizes for the combined mental health outcomes were relatively similar across the range of target groups: 0.50 for clinical and 0.62 for non-clinical populations and this difference is not significant. Likewise the effect size was 0.51 both for people recruited because of a somatic condition and for those with a mental health problem. Effect sizes for mental health were not particularly influenced by the length of intervention, self-reported practice, risk of bias, or whether analyses were done as intention to treat or per protocol, but they were positively correlated with course attendance. Only nine studies included follow-up data; the effects diminished over time except in one study in which refresher classes were held. Very little data were found on social functioning, and no information at all on side effects and costs.

AUTHORS' CONCLUSIONS

MBSR has a moderate and consistent effect on a number of measures of mental health for a wide range of target groups. It also appears to improve measures of personal development such as empathy and coping, and enhance both mindfulness, quality of life and improve some aspects of somatic health. Hardly any included

studies measured either social function or work ability. There is a paucity of data on long-term effects.

1 Background

1.1 DESCRIPTION OF THE CONDITION

Stress is ubiquitous in modern life. While some people are prompted to respond positively to it, more often than not it exerts a negative influence. At its worst, stress destroys lives. The demands of life are external but stress is generated from within and stressors may be real or imagined. How we handle situations, persons and emotions – in other words, how we become stressed or manage to keep calm – is central to staying healthy, coping with illness and enjoying life. These are skills that can be practised and exercised.

Prevalence rates for distress and mild to moderate psychological problems are high among children, adolescents and adults, and associated chronic musculoskeletal pain is common. While our understanding of such widespread problems is limited, we do know that stress is probably both a cause and a consequence of them.

Stress is also part of our everyday working life. In a series of surveys undertaken at five year intervals in the European Union, stress was identified as the second most common threat posed by working environments and an issue affecting a fifth of the workforce at any time (European Risk Observatory, 2009). Stress can lead to an increased risk of disease, including cardiovascular disease (Cohen, 2007; Chandola, 2008). Likewise there is mounting evidence that stress caused by traumatic life events increases the risk of chronic somatic and psychological problems affecting health and quality of life (McEwen, 2008); adverse childhood experiences are especially harmful (Brown, 2009).

1.2 DESCRIPTION OF THE INTERVENTION

Mindfulness-Based Stress Reduction, or MBSR, is a well described group-based mind-body intervention programme that has received considerable research attention (Kabat-Zinn 1990). 'Mindfulness' may be defined as the ability to non-judgementally observe sensations, thoughts, emotions, and the environment while, at the same time, encouraging openness, curiosity and acceptance. An MBSR programme to develop and strengthen this skill was developed by the University of Massachusetts Medical Center in 1979 as an intervention designed to relieve stress

and help people cope with illness. This programme is now offered at several hundred healthcare institutions in the USA and Europe (Santorelli, 1999). Target groups include people with chronic physical pain, illnesses such as cancer, or mental illnesses, including anxiety, depression or burnout. In addition, the programme has been applied to non-clinical populations, including students, therapists and prison inmates.

The standard MBSR mindfulness training is an eight week group programme with weekly sessions of between 2-2 ½ hours and an all-day session in the last two weeks. Shorter weekly sessions (30-90 minutes) may be offered as an alternative, and some programmes omit the all day session entirely. Weekly sessions include mental and physical mindfulness exercises as standardised core elements. These include: body scan exercises in which 'neutral attention' is directed towards sensations from the different parts of the body when sitting or lying still (in other words, participants observe these sensations without trying to achieve any particular objective); mental exercises focusing attention on breathing; physical exercises focussing on an awareness of bodily sensations; and practising being fully aware during everyday activities by using breathing as an anchor for attention. Essential to all parts of the programme is the development of an accepting and non-reactive attitude to what one experiences in each moment. The intervention is rooted in ancient Buddhist Vipassana ('insight') and Shamatha ('focussed') meditation and yoga exercises. However, it is free from religious purpose or affiliation and is described using only Western terminology.

In addition to the exercises, information (and a discussion) is provided and discussion is facilitated on the topics of stress, stress management, and how to apply mindfulness to interpersonal communication and everyday situations. Each group session includes time for participants to reflect together on what they experience while practising mindfulness. Outside the sessions, participants are encouraged to practice each day for 30-45 minutes while listening to audiotapes and using the guided exercises (these include body-scanning, the mindfulness sitting exercise which focuses on breathing, as well as yoga stretching exercises). The group usually includes 10-30 members and is led by one or two trained instructors.

1.3 HOW THE INTERVENTION MIGHT WORK

The MBSR programme provides systematic training in mindfulness as a self-regulation strategy to reduce stress and manage emotion. The programme is intended to foster greater awareness of what happens in each moment through the application of an attitude of acceptance. MBSR is designed to help people avoid habitual negative thoughts, emotions and behavioural patterns. Instead, increased awareness and acceptance is seen as allowing for new ways to respond and cope both in relation to oneself and the wider world. Mindfulness training has been linked to changes in areas of the brain responsible for affect regulation, and to stress impulses reactions; in turn, these changes influence body functions such as

breathing, heart rate and immune function (Davidson, 2003; Lazar, 2005; Hölzel, 2010).

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

MBSR is increasingly widespread and it is important therefore to find out whether it is effective, for whom, and under what circumstances. Knowing such details can help to guide future research. A number of recent published reviews have suggested overall that MBSR may be effective in reducing the symptoms of anxiety, depression and stress. However, most such reviews have been narrative reviews rather than meta-analyses. This has led Hofmann et al. (Hofmann, 2010) to argue that "the field has become saturated with qualitative reviews" (p.170).

Quantified effect sizes in other meta-analyses we have identified were based on randomised controlled trials combined with quasi-experimental design studies (Baer, 2003; Carmody, 2009; Grossman, 2004; Ledesma, 2009; Hofmann, 2010). Baer found an overall Hedges' g-value of effect size of 0.59 for all outcomes, but this included both MBSR and Mindfulness Based Cognitive Therapy (MBCT) studies. Similarly, Carmody calculated an overall Hedges' g-value for effect size of 0.63 for psychological outcomes, but included control groups with both treatment-as-usual, waiting-list, and alternative treatments. Grossman reported an overall Cohen's d-value of effect size of 0.5 for studies of MBSR with combined outcomes of physical and mental well-being. Hofmann also included MBSR and other interventions like mindfulness based cognitive therapy in the same meta-analysis, reporting an overall Hedges' g-value of effect size for anxiety of 0.63 and 0.59 for mood symptoms. Bohlmeijer et al. (2010) included only controlled MBSR studies, and calculated an overall Hedges' g-value of effect size of 0.47 for anxiety outcomes and 0.32 for psychological distress outcomes. However the authors grouped together studies using waiting-list controls and studies where the control group was offered alternative active treatment.

A health technology assessment report from 2007 (searches conducted up to 2005) identified five broad categories of meditation practices of which mindfulness meditation was one (Ospina, 2007). In this instance, the meta-analysis was focussed on effects on hypertension, cardiovascular disease and substance abuse, and it did not specifically evaluate MBSR.

2 Objectives

To assess the effectiveness of MBSR in improving health, quality of life, and social functioning in adults.

3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

Studies of mind-body interventions such as MBSR are especially prone to bias introduced by the self-selection of study participants to intervention or control groups. For this reason, we have only included RCTs in this systematic review. We expected to find a sufficient number of such studies.

3.1.2 Types of participants

MBSR is a general method for self-regulation that has been applied to a variety of target groups: we therefore included all populations. There were two exceptions to this approach: both children (under the age of 18) and persons with cognitive impairment or severe mental illness were not included. This was because children are less able to be self-aware; MBSR is dependent on the ability of individuals to pay attention and to be able to remember from one moment to the next.

3.1.3 Types of interventions

We included studies of MBSR training programmes which had been based on the protocol elements specified by John Kabat-Zinn (Kabat-Zinn, 1990). This meant that to be considered, the intervention had to be explicitly termed 'MBSR' and contain all four of the requisite core elements, namely: body-scan exercises, mental exercises focusing attention on breathing, physical exercises focussing on the awareness of bodily sensations, and the practice of being fully aware during everyday activities. Studies of varying MBSR course duration and intensity were included. Studies that combined MBSR with other therapeutic approaches, such as cognitive therapy or art therapy, were excluded.

Waiting lists and treatment-as-usual were acceptable control groups. RCTs in which the control group had been offered alternative active treatment were also included, but these were analysed separately.

3.1.4 Types of outcomes

Primary outcomes were measures of mental health (anxiety, depression and stress/distress), somatic health (self-reported physical health inventories and somatic measures related to antibodies, heart rate or respiratory functions) and quality of life (only including measures designed specifically to measure quality of life, such as the WHO Quality Of Life Inventory). Secondary outcomes were social functioning (such as the ability to work, sickness rates, and self-reported measures of social functioning e.g., The Social Functioning Questionnaire SFQ) and measures of personal development (e.g., self-acceptance, empathy, coping and forgiveness). The different measurement scales and outcome groups are listed in additional Tables 4 and 5.

3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

3.2.1 Electronic searches

Electronic searches of bibliographic databases and open websites were conducted. We examined reference lists from the articles under consideration and asked key researchers within the field for information. In addition, we searched for 'grey literature' trials and for ongoing studies registered at www.clinicaltrials.gov. No publication, geographic, or language restrictions were applied.

3.2.2 Search terms

The following sources were searched at the outset of the project in July 2008 and again in September 2010:

MEDLINE
AMED (Allied and Complementary Medicine)
PsycINFO
EMBASE
Ovid Nursing Full Text Plus
British Nursing Index and Archive
Cochrane Central Register of Controlled Trials (CENTRAL)
SIGLE
Web of Science®
SveMed+
Dissertation Abstracts International
ERIC
Social Services Abstracts
Sociological Abstracts
International Bibliography of Social Sciences
ProQuest

The Cochrane Collaboration' search strategy includes a RCT search filter for identifying randomised trials in MEDLINE and this was used when searching this database. This filter was subsequently modified for other database searches. Appendix 15.1 contains full documentation of all the search terms used.

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Two reviewers independently read the titles and available abstracts of the studies in order to exclude those that were obviously irrelevant. Any citation deemed potentially relevant by at least one reviewer was retrieved in full text form. Multiple papers reporting on the same study were linked together. Two reviewers (one with content expertise and the other with methodological expertise) independently read all the retrieved studies in order to determine whether they met the selection criteria (Appendix 12.1). The reviewers were not blinded to journal names, author names, author affiliations or the study results. Disagreements about the relevance of particular studies were resolved during discussions with a third reviewer with methodological expertise. Correspondence with investigators, where necessary, helped to clarify study eligibility. Those studies that met the screening criteria but did not meet all the inclusion criteria are listed in Section 11.2 (Characteristics of Excluded Studies), together with the reasons for their exclusion.

3.3.2 Data extraction and management

Information on study design and implementation, sample characteristics, intervention characteristics, and outcomes was extracted from studies. This information was entered on a paper form (see Appendix 15.3). The data extraction form included a coding list which was piloted on two of the selected studies at the outset of the data extraction phase. Two reviewers independently extracted data from all the studies. Disagreements were resolved through discussions with a third reviewer with relevant methodological expertise.

3.3.3 Assessment of risk of bias in included studies

Risk of bias was evaluated according to the criteria stated in the Cochrane Handbook (Higgins, 2008). Two independent reviewers assessed the issues of sequence generation, allocation concealment, the blinding of outcome assessors, the completeness of outcome data, outcome reporting, and any other potential sources of bias. Using the GRADE approach, further analysis of the quality of evidence was undertaken related to each of the key outcomes (Guyatt, 2008; Higgins, 2009). The quality of the body of evidence for each key outcome was rated as 'High', 'Moderate', 'Low', or 'Very Low'.

3.3.4 Measures of treatment effect

As expected, only outcome data from (a number of) ordinal scales were found; no binary data were identified. We therefore calculated standardised mean differences (as Hedges' g-values) using the Comprehensive Meta Analysis program which is able to accept a variety of different data formats (Borenstein, 2009). Effect sizes were calculated for gain scores (post-minus pre-measurements in the control group were subtracted from post-minus pre-measurements in the treatment group). These results were then standardised using the post-test pooled standard deviation. In four studies the effect sizes were calculated from other data; in Astin (1997) from the F-values for the difference in change in the MBSR and control group; in Cohen-Katz (2005) and Creswell (2008) from the difference in mean change between the MBSR and control group and the corresponding p-values; and in Grossman (2010) from the difference in mean change between the intervention and control group and the corresponding F- values.

3.3.5 Unit of analysis issues

We assessed the unit of analysis of all the trials: one study was found to have randomised couples rather than individuals. The robust standard error analysis we used (see below) was able to process the data while accommodating for such dependencies.

3.3.6 Dealing with missing data and incomplete data

Study authors were contacted if missing information was needed (related, for example, to standard deviations). Most authors did not respond or were unable to retrieve the data. Some studies presented data visually and this made it possible to read data from the graphs (Anderson, 2007; Davidson, 2003; Plews-Ogan, 2005; Shapiro, 1998; Williams, 2001). In other instances we calculated standard deviations using standard errors, confidence intervals, t-values or p-values that related to the differences between the means in two groups (Anderson, 2007; Davidson, 2003; Lengacher, 2009; Moritz, 2006; Plews-Ogan, 2005; Williams, 2001). In only one instance was a study excluded from the analysis due to a lack of information (no SD or SE) (Alterman, 2004).

Means and standard deviations values were based on those stated in the original study publications, irrespective of how such missing data may have been processed in the primary analysis.

3.3.7 Assessment of heterogeneity

The degree of heterogeneity was evaluated both informally (by checking the overlap of the confidence intervals), and statistically (by estimating the total heterogeneity using tau2 values (where <0.05 indicates low heterogeneity). The percentage of the total variability due to heterogeneity was estimated using I2 values; 0% representing

no heterogeneity, 50% indicating moderate heterogeneity and 75% indicating high heterogeneity (Higgins, 2003).

3.3.8 Assessment of publication bias

We investigated possible reporting biases using funnel plots and tested for funnel plot asymmetry using Egger's regression test (Egger, 1997).

3.4 DATA SYNTHESIS

All analyses were conducted with random effects models. When evaluating the outcomes for mental health, the results were first grouped separately into four constructs, namely: anxiety, depression, stress/distress and other measures of mental health (see Table 13.4). The majority of the studies identified included multiple measures of the same construct, and the sizes of effect were typically calculated for the same individuals. Since the covariance structure of these effect sizes was not reported in any of the studies, we used a newly developed robust statistical technique for estimating standard errors under such circumstances (Hedges, 2010).

This technique calculates standard errors using an empirical estimate of the variance: it does not require any assumptions regarding the distribution of the effect size estimates. Those assumptions that are required are minimal and generally met in practice. Simulation studies show that both confidence intervals and p-values generated this way typically reflect the correct size in samples, requiring as few as ten studies for the estimation of an average effect size, or between 20-40 studies for the estimation of a slope. This more robust technique is therefore beneficial because it allows all of the effect size estimates to be included in meta-analyses.

An important feature of this more robust standard error analysis is that the results are valid regardless of the weights used. For efficiency purposes, we calculated the weights using a method proposed by Hedges et al (Hedges, 2010). This method assumes a simple random-effects model in which study average effect sizes vary across studies (τ^2) and the effect sizes within each study are equicorrelated (ρ). The method is approximately efficient, since it uses approximate inverse-variance weights: they are approximate given that ρ is, in fact, unknown and the correlation structure may be more complex. For the results we calculated, weights were used based on estimates of τ^2 and I^2, where $\rho = 0.80$. Though not reported here, sensitivity tests were also conducted using a variety of ρ values; these indicated that the general results and estimates of the heterogeneity (τ^2 and I^2) were robust to the choice of ρ.

In addition to estimating an average effect for each of the four mental health constructs, we also calculated an average effect for mental health across all the studies and measures. Clinicians commonly view anxiety, depression and psychological stress/distress as different constructs. However, the actual questions

used in the different inventories (many of which were often fairly similar) and the measurement of correlation (which were consistently high) cast doubt on whether the standard methods of measuring anxiety and depression do, in fact, always tap into different constructs in practice. The described analyses are therefore an explicit attempt to look at this difficult issue using both such approaches.

This robust standard error approach was also used to evaluate the outcomes of somatic health, quality-of-life measures, personal development and mindfulness, as well as for varying lengths of follow-up.

3.4.1 Subgroup analysis, moderator analysis and investigation of heterogeneity

Theoretical and empirical reasons suggest that, by and large, one may expect similar effects across chosen target groups, varieties of an intervention, and relevant outcomes. Nevertheless the following subgroup analysis was undertaken in order to explore potential differences in effects on mental health:

- Clinical and non-clinical samples (expecting a somewhat larger effect in studies of patients with established health problems compared to studies where participants were recruited from the general population)
- Psychological and somatic conditions (expecting a somewhat larger effect in studies of participants with psychological distress compared to studies of people with somatic problems)
- Effect of length of the MBSR intervention (expecting a somewhat smaller effect in studies that used a shorter MBSR programme compared to a standard approach)
- Effect of compliance (expecting a somewhat larger effect in studies where participants generally attended most of the programme versus studies where attendance was lower, and in studies where people spent more rather than less time practising at home)
- Effect of follow-up time (expecting effect sizes to diminish over time in studies with a longer follow-up period)
- Risk of bias (expecting a larger effect in studies with higher risk of bias). In this particular analysis we used the risk of bias scores as a scale
- Whether or not the authors claimed to have done an intention to treat (ITT) analysis (expecting somewhat lower effect estimates in studies that reported ITT analyses).

Each of these questions was investigated using a separate bivariate regression model. Each model was estimated using the robust standard error method outlined above (Hedges, 2010). Since this robust standard error method uses degrees of freedom based on the number of studies (rather than the total number of effect sizes), we elected to apply individual regression models instead of combined models. In Appendix 12.4 we provide a correlation matrix for the following variables: clinical (vs. non-clinical) samples, clinical somatic (vs. clinical psychological) samples,

length of MBSR invention, attendance, follow-up time, risk of bias, and if the analysis was based on an intention-to-treat effect.

4 Results

4.1 RESULTS OF THE SEARCH

The original search in July 2008 identified 2,162 potentially relevant articles; a second search in September 2010 found 972 additional references. Based on our screening and inclusion criteria 31 studies were included in the review.

4.2 DESCRIPTION OF THE STUDIES

4.2.1 Included studies

The characteristics of the included studies are listed in Table 10.1 and 11.1. 20 studies recruited people with health problems: 13 of these included patients with somatic conditions (musculoskeletal disease, cancer, other chronic illness, HIV, cardiovascular disease and substance abuse (Bränström, 2010; Creswell, 2007; de Vibe, 2006; Grossman, 2010; Lengacher, 2009; Monrone, 2008; Plews-Ogan, 2008; Pradhan, 2007; Sephton, 2007; Speca, 2000; Speca, 2000; Surawy, 2005; Tacon, 2003). Seven studies included persons with psychological conditions (stress/distress, anxiety, mood disorder, aggression and stuttering) (Alterman, 2004; de Veer, 2009: Koszycki, 2007; Moritz, 2006; Nyclicek, 2008; Vieten, 2008; Willliams, 2001). 11 studies included people from the general population (Anderson, 2007; Carson, 2004; Cohen-Katz, 2005; Davidson, 2003; Klatt, 2009; Shapiro, 2005); five such studies used student samples (Astin,1997; Jain, 2007; Murrey, 2004; Oman, 2008; Shapiro, 2005). One study included prisoners (Murphy, 1995). Altogether 1,942 persons were randomised; 26 studies compared MBSR with waiting-list or treatment-as-usual controls.

Three of the studies included another intervention group in addition to the waitlist control group (Jain, 2007; Moritz, 2006; Plews-Ogan, 2005) and in these cases we used only the data from the comparison of MBSR with the waitlist controls. The results of four additional included studies were reported separately because they compared MBSR with other active interventions. Creswell (Creswell, 2008), for example, compared a standard eight-week MBSR course with a one-day MBSR course. Koszycki (Koszycki, 2007) compared MBSR with MBCT. Murphy (1994) compared MBSR with progressive relaxation training. And Oman (2008) compared MBSR with a generally similar mindfulness training called Easwaran's Eight-Point

Program (EPP), and with treatment-as-usual. In this paper, only combined data from the groups receiving MBSR or EPP were reported.

In addition, we included – but could not use – data from one study (Alterman, 2004; see 'Studies where data could not be used in the meta-analysis'). Two studies were reported in two publications: Sephton (Sephton, 2007) also presented results in Weissbecker (Weissbecker, 2002), and one study was presented both by Tacon (2002) and Robert-McComb (2004).

4.2.2 Excluded studies

188 studies were excluded either because they were neither primary studies nor RCTs, or because the intervention did not conform to the MBSR protocol. Reasons for exclusion are listed in Table 11.2.

4.2.3 Studies awaiting classification

Four studies are awaiting classification (Esmer, 2010; Schmidt, 2011; Vøllestad, 2011; Wong, 2011).

4.3 RISK OF BIAS IN INCLUDED STUDIES

4.3.1 Allocation concealment

The quality item with the lowest score was allocation concealment. Only nine studies reported adequate concealment of allocation. Most studies failed to state clearly how randomisation had been achieved.

4.3.2 Blinding

Blinding of participants and providers is impossible to achieve in studies where people receive stress reduction interventions. It is, however, possible to blind the assessors and this was done in ten studies.

4.3.3 Incomplete outcome data

Attrition was 15% overall and 25 studies reported all data, while only four studies had a definite incomplete reporting of all results. Nine studies reported intention to treat analyses data, and they used the last observation carried forward as the method for imputing missing data.

4.3.4 Selective reporting

Assessing publication bias, we detected no important funnel plot asymmetry (see Figure 13.13) and the Egger's r-test for funnel plot symmetry indicated an intercept value of 0.95 (95% CI -0.24, 2.15). When applied, a Fail-Safe N (Rosenthal,1979) analysis showed that the number of missing trials needed to raise the p-value to >0.05 was 689; a Fail- safe N (Orwin, 1983) analysis showed that the number of

missing studies with zero effect – that would reduce the Hedges's g-value to <0.2 (indicating a small effect) – was 44.

4.3.5 Other sources of bias

Many studies are carried out by researchers believing in the intervention and who also provide the intervention and are responsible for the assessment. Other sources of bias were different assessors doing semi-structured interviews with the participants at baseline and after the intervention (Alterman, 2004), baseline differences between groups not accounted for (de Veer, 2009), some participants changed group after randomization (Oman, 2008), and some participants were given additional sessions with a therapist (Surawy, 2005).

4.4 EFFECTS OF THE INTERVENTIONS

4.4.1 MBSR vs. waiting-list/treatment-as-usual

All effect sizes are expressed using Hedges' g-values (Hedges 1985), and conventionally a value of 0.2-0.5 signifies a small effect, 0.5-0.8 a moderate effect and values >0.8 signifies a large effect of the intervention (Cohen, 1988). Positive values indicate beneficial effects.

Converting effect sizes to percentile values is a useful way to illustrate possible clinical importance: an effect size of 0.53, for example, indicates that the average person in the intervention group will be placed at the 30th score percentile for the control group.

Table 11.5 and Figures 13.4-13.7 show that the average effects were fairly similar for anxiety (0.53, 95% CI 0.43, 0.63), depression (0.54, 95% CI 0.35, 0.74), stress/distress (0.56, 95% CI 0.44, 0.67) and other measures of mental health (0.48, 95% CI 0.34, 0.61). Values for heterogeneity, from tau square analysis, were very small and ranged from 0 to 0.003. 26 studies with 79 different outcome variables (of anxiety, depression, stress/distress and various other measures of psychological functions) contributed to the meta-analysis of mental health in which the robust standard error approach was used (Figure 13.8). The overall effect size for the composite measure of 'mental health' was 0.53 (95% CI 0.46, 0.61). Again, heterogeneity across the studies was low: the values were tau2 = 0 and I2 = 0.

The effects on measures of personal development (0.50, 95% CI 0.35, 0.66), quality of life (0.57, 95% CI 0.17, 0.96), and mindfulness (0.70, 95% CI 0.05, 1.34) were also of moderate size (Figures 13.9-13.11). However, as shown in Figure 13.12, the effect size was somewhat smaller for measures of somatic health (0.31, 95% CI 0.10, 0.52). Results for quality of life and mindfulness were somewhat heterogeneous across trials with tau2 values of 0.07 and 0.40.

For mental health as a composite outcome, there was an insignificant difference in effect size between studies in which persons were recruited because of stress or diagnosed problems (in other words, from clinical populations) and target groups which had been recruited from the general population (p=0.19). Likewise, studies of people with somatic problems as entry criteria achieved a very similar effect on average to those studies in which people with psychological difficulties were recruited (p=0.96) (Table 11.6).

The effect size for 'mental health' rose slightly with increasing intervention length (between 6 and 28 hours), but again this increase was not statistically significant (p=0.16).

18 studies reported on course attendance which ranged from 65% to 92%. There was a significant increase in effect on mental health for each hourly increase in attendance (reported as averages per study) (p <0.01). Only 13 studies described self-reported time spent practising MBSR techniques at home (with an average range per study of between 7 and 45 minutes). In this analysis, length of self-reported time spent practicing MBSR techniques at home did not appear to increase mental health outcome scores (p=0.44).

For follow-up time, we first compared the effect at post-intervention in studies with data (9 studies) and without follow-up data (17 studies) and found no difference. We then assessed the effect of the number of months of follow-up on the reported effect size. There was a slight, but statistically significant, decrease in effect size on 'mental health' for each additional month of follow-up (p<0.05).

A slight decrease in effect size was seen as risk of bias increased, but this finding was not statistically significant (p=0.29). Neither were there significant differences in effect sizes between those studies reporting results as intention to treat (ITT) analyses and studies reporting per protocol data (p=0.13).

Mindfulness was measured in seven studies (measures used are listed in additional Tables 2 and 3): six reported increases at the post-intervention stage, while one study showed an increase only at four months follow-up (Pradhan, 2007). Two studies performed mediation analysis, suggesting that the effect on the outcomes were mediated by the increase in mindfulness scores (Bränström, 2010, Nycklicek, 2008). Because few studies measured mindfulness and because we do not have access to data on individuals in the studies, further mindfulness mediator/moderator analyses could not be performed.

Unfortunately, very few studies measured social functioning. One study reported on ability to work, but the numbers of people involved were too small to allow conclusions to be drawn. There were no reports on adverse events or costs in any of the studies.

4.4.2 MBSR vs. Alternative active interventions

The data from these studies are treated separately and the effect sizes are not pooled.

Koszycki et al. (2007) compared an eight-week (27.5 hour) MBSR course with a 12-week (30 hours) cognitive behavioural therapy course for 53 patients with moderately severe social anxiety disorder. All sessions were videotaped and reviewed to assess protocol fidelity. Homework forms were reviewed each week. Both interventions produced meaningful clinical changes. The MBSR group showed high to moderate beneficial effect judged by within group Hedges' g-value effect sizes on measures of social anxiety (1.42, CIs not given), mood (0.66), disability (0.63), and quality of life (0.53). Patients in the cognitive therapy group improved significantly more than those in the MBSR group in terms of social anxiety. There were no between-group differences in the other outcomes. The MBSR programme had a dropout rate of only 15%.

Oman et al. (2008) compared an eight-week (12 hour) MBSR course with an alternative eight week (12 hour) programme (on Easwaran 8-point mindfulness), while the third group was a wait-list control group of 44 college students. Because the unreported data results were similar for both the MBSR and EPP participants, both groups were analysed together and compared to the wait-list control group. The between-group Hedges' g-values for effect sizes for the main outcomes at post-intervention (and at the eight weeks follow-up) were 0.44 (0.50) for perceived stress, 0.33 (0.44) for rumination, and 0.33 (0.30) for forgiveness (confidence intervals not given). There were no significant changes in measures of hope.

Murphy (1994) compared the effect of a six-session (12 hour) MBSR course with six two-hour sessions of progressive muscle relaxation (PMR) for 31 inmates who had alcohol abuse and aggression problems. No substantial differences were found on measures of anger (using the State Trait Anger Expression Inventory), egocentricity (using Self Focus Sentence Completion), and stress reactivity measured by the post-stress testing of salivary cortisol at the post-intervention stage.

Creswell et al. (2008) compared an eight week (24 hour) MBSR course with a one day (6 hour) MBSR course among 48 HIV+ people experiencing distress and scores of >4 on the Patient Health Questionnaire-9 scale). CD4+ T lymphocyte counts were shown to decrease in the one-day control group, but not among participants in the full MBSR course. The between-group Hedges' g-value of effect size was 0.74 (CI not given).

4.4.3 Studies where data could not be used in the meta-analysis

Alterman et al. (2004) compared the effect of an eight-week (23 hour) MBSR course with treatment-as-usual for 31 substance-abuse recovery inpatients at post-intervention and at five months follow-up (Alterman, 2004). The data were analysed using repeated measures analysis of variance at three time points. The intervention

group improved more than the control group in terms of self-reported medical problems when analysed as a group over three follow-up times (p=0.007). However, because only mean values were reported, a Hedges' g-value of effect size could not be calculated. No significant group differences were found for measures of psychological health.

5 Discussion

5.1 SUMMARY OF THE MAIN RESULTS

It is encouraging to see that the MBSR mind-body intervention has been analysed in substantial numbers of randomised controlled trials. This review has reported on more trials than ever before: 31 RCTs were selected, with a combined total of 1,942 participants. The overall effect size for the combined outcome of mental health was moderately large (Hedges' g-values = 0.53, 95% CI 0.46, 0.61). The effect sizes were remarkably similar across a range of target groups (with mild to moderate distress), intervention forms, outcome measures and settings. Heterogeneity was therefore low.

Many of the studies we included provided several different measures of the same construct and outcome measurements that were obviously interdependent. Failure to account for such dependencies – in other words, calculating an average 'anxiety effect' based on measurements with different anxiety scales – necessarily results in erroneous standard errors and will compromise any inferential statistics generated. Deciding on a criterion for electing only one outcome measure to include in the meta-analysis can be equally problematic. Statistical dependencies were also evident in follow-up measures post-test. As far as we know, this study is amongst the first to utilise a new method for estimating robust standard errors under such circumstances. This method makes it possible to use more information in the data-set than has traditionally been the case (Hedges, 2010).

5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE

A number of MBSR evaluations have been published in this specialist knowledge field in the last decade. Baer identified four randomised trials in 2003 (Baer, 2003) and all of these are included in our study. Grossman (Grossman, 2004) reported on seven RCTs in 2004: one of these we classified as not being a randomised trial (Perkins, 1998). Carmody (2009) found 11 controlled studies: nine were classified by us as RCTs.

Later reviews have focussed on specific target groups. Ledesma & Kumano, for example, identified four trials on cancer patients (Ledesma, 2009). We have excluded three of these from our analyses – two because they included elements

other than those stipulated in the traditional MBSR protocol (Herbert, 2001; Monti, 2005), and one because it took the form of a quasi-experimental study (Shapiro 2003). Hofmann identified seven randomised trials measuring anxiety or depression (Hofmann, 2010) and all of these are included in our study. Bohlmeijer identified eight RCTs studying patients with a chronic medical condition (Bohlmeijer, 2010). Seven of these are included in this work, while one was excluded because it deviated from the standard MBSR protocol (Monti, 2005). Chiesa (Chiesa, 2009) included seven trial studies of healthy people, and all of these are included in our study.

Of the 26 studies used in our meta-analysis, five included persons with various psychological problems; 11 of the studies targeted people with various somatic conditions; and ten recruited people from the general population. The intervention effect has thus been evaluated across a broad spectrum of target groups. Study settings in a number of different countries (Norway, Sweden, Germany, Switzerland, Holland and the USA) contributed to the analysis, further serving to increase the applicability of the evidence.

Studies that implemented major modifications to the standard MBSR protocol were not included. However, studies of varying intervention length were accepted if the researchers had adhered to the MBSR principles as stated by Kabat-Zinn (Kabat-Zinn, 1990). Relatively few studies included follow-up data, and none included long-term follow-up data: the evidence therefore for the long-term effects of the intervention is clearly limited. All control groups received no treatment or treatment-as-usual. Control conditions therefore varied and it was often difficult to determine what the alternative conditions had been.

Unfortunately, only two trials provided data on social functioning (Nyklicek, 2008; de Vibe, 2006) and the ability to work (de Vibe, 2006) and there was a paucity of data related to functional outcomes. No explicit reporting on possible adverse effects or costs was provided. Such information should be addressed in future trials.

5.3 QUALITY OF THE EVIDENCE

The quality of the studies varied and the overall risk of bias was high for several studies (Davidson, 2003; Cohen-Katz 2005; Alterman, 2004; Astin, 1997; Lengacher, 2009; Murray 2004; Plews-Ogan, 2005; Shapiro, 2005; Weissbecker, 2002). However, it was encouraging that high-quality trials were also found (Bränstöm, 2010; Grossman, 2010; Jain, 2007; Moritz, 2006; Morone, 2008; Nyklicek, 2008; Pradhan, 2007; Speca, 2000). Effect sizes did not, however, differ significantly between studies carrying different risk of bias ($p = 0.32$, see additional tables 4). Judgements about evidence and recommendations in healthcare are complex. The GRADE system has been developed to improve judgements about the quality of evidence (GRADE, 2008). Grading of the evidence showed that the quality is high for evidence of effect on the composite score of mental health as well as for

measurements of stress/distress, but low for measurements of effect on quality of life, and moderate for effects on other outcomes (Figure 13.14).

5.4 POTENTIAL BIASES IN THE REVIEW PROCESS

All steps in the analyses were undertaken by researchers with content and methodological expertise.

Estimation of effects using the more robust method of variance estimation we applied showed typically similar effect size estimates compared to estimates made using the conventional method. The confidence intervals, however, were narrower. It was notable that we were able to make use of most of the data provided in the studies. We also avoided the often haphazard choice of which outcome to include in a meta-analysis in those instances where several measures of the same construct were presented in the primary studies. We anticipate that this new statistical method will become a standard technique in future meta-analysis.

5.5 AGREEMENTS AND DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS

Overall, the effect sizes we estimated are relatively similar to the findings presented in other review evaluations of MBSR. This holds true for measures of anxiety, depression, stress, somatic health, and quality of life. This was not the case, however, with regard to Toneatto's study in which MBSR was shown to have no effect on depression and anxiety (Toneatto, 2007). Toneatto's finding though, we would contend, was due to comparisons of MBSR being made with alternative interventions in studies with varying designs. We suggest that the effect size compares favourably with a recent meta-analysis of psychological treatments of depressive symptoms in patients with medical disorders (van Straten, 2010). After removing two outliers, the data showed an overall effect size of d=0.42 (95% CI 0.27, 0.58) for the 15 controlled studies comparing psychological treatments with a wait-list or care-as-usual control group. Likewise, the effect size is in the same range as those recently reported for interpersonal psychotherapy for depression (Cuijpers, 2011). The potential for MBSR as a useful intervention for improving mental health, we argue, is therefore promising.

Based on the assumption that many self-reported mental health outcomes are actually rooted in similar aspects of mental functions, we developed a single composite measure of mental health based on the outcomes for anxiety, depression, stress/distress and other mental health outcomes. These latter outcomes included measures of emotional disturbance and regulation, anger, worry, rumination, relaxation, and life orientation. This mental health measure captured data from all 26 studies; the measure included 79 of the 132 outcomes. Three other reviews (that also included non-randomised studies) measured 'mental health' as a single

construct and the results were in the same range as our own (Baer, 2003; Grossman, 2004; Carmody, 2009).

5.5.1 Subgroup analyses

All subgroup analyses were conducted using the single composite mental health outcome measure as the dependent variable. The correlation matrix of the variables is shown in additional Table 11.6. A somewhat larger effect size among patient populations (16 studies) than non-clinical populations (ten studies) was expected. We hypothesised that effects would be larger in clinical populations with psychological problems (five studies) than in somatic clinical populations (11 studies). However, neither of the comparisons showed any significant difference, and both Grossman (2004) and Carmody (Carmody, 2009) reported similar findings. A possible explanation for this is that all the studies included participants who were self-selected. Given that the MBSR intervention is a well-known intervention for stress-related problems, those included in the studies might therefore be expected to be more similar in terms of their level of mental health problems than the different group categories might suggest. Another explanation for the similarity of effects across the different groups in terms of distress is because the studies on somatic health problems mainly included patients with chronic musculoskeletal problems, and the studies on psychological problems included only patients with minor mental problems.

However, there is evidence to suggest that the effect is larger for people who have substantially higher levels of mental health problems. One study which included patients with clinical psychiatric diagnoses (Koszycki, 2007) found a larger effect size, as did Grossman (2010) and de Vibe (2006), for subgroups of patients with higher levels of psychological symptoms. More studies should therefore attempt to elucidate which groups would benefit most from MBSR interventions and whether or not there is a floor effect (i.e., a particular level of symptoms that would be needed to demonstrate an effect).

Among the nine studies with follow-up data at 1-6 months, the effect size was shown to decrease slightly over time. More studies with longer follow-up periods are thus needed. Most trials offered the intervention to the control group immediately after the end of the intervention period. While this may be understandable from a practical or perhaps an ethical point of view, doing this destroys the possibility of examining evidence on long-term effects. One study (Pradhan, 2007), for example, gave three refresher classes in the four months follow-up period. A significant increase in the effects on psychological distress, well-being and mindfulness at follow-up was found when compared to post-intervention. We recommend further investigation to identify what will be required to maintain such treatment effects over time.

We expected the lengths of the intervention, attendance and home practice to influence the effect size to some degree, but only found this to be true for

attendance. The length required for MBSR course interventions to have an effect is thus still unknown. It should also be noted that the effect may occur due to moments of insight which lead to a change in the way people view themselves and the world. This may be due as much to a person's readiness to change as from the length of an MBSR course. In a more detailed analysis of dose-response, Carmody (2009) did not find any significant effect from the length of an MBSR course or assigned home practice. But we do not know, however, anything about the quality of the actual practice undertaken. One could argue therefore that a 30-minute daily practice routine which lacks attention or focus may actually be less effective than learning instead to be mindful in everyday life – this would be very difficult to measure and evaluate.

Furthermore, different types of practice may have different effects on different outcomes, as shown in a pre-post study of 174 participants assigned to different types of MBSR classes (Carmody, 2008). When analysed on the basis of more careful recording, Rosenzweig (2010) showed that the effect varied both as a function of clinical condition and compliance. A recent uncontrolled study showed that home practice predicted not only reductions in self-reported stress, but also changes in brain grey matter density in the right amygdala, an area involved in stress reactions (Hölzel, 2010).

Attendance was found to be associated positively with the effect of the MBSR intervention in seven of the 11 studies examining this possible predictor. Attendance may be a measure of motivation or an indicator that participants found the intervention useful. It may simply be that seeing a course through to the end is necessary for a course to have effect. We suggest that this issue should be investigated further. This could be achieved by, for instance, trying to measure motivation, interviewing those who complete the courses as well as any dropouts, and measuring the effect of MBSR several times during the course period in order to explore whether attendance mediates the effects.

Eight studies reported intention to treat (ITT) data, and showed a slightly smaller mental health effect size (0.47) relative to the 18 studies with non-ITT data (0.59). The difference, however, was not significant. On the whole, attrition was low (ca. 15%). The data suggested no significant differences in average mental health effect size due to variations in risk of bias. However, it was somewhat difficult to distinguish between inadequate reporting and a de facto high risk of bias.

6 Authors' conclusions

6.1 IMPLICATIONS FOR PRACTICE

There is moderate- to high-quality evidence of a consistent and moderately large effect of Mindfulness Based Stress Reduction (MBSR) on health and quality of life. The intervention appears to improve measures of personal development, including empathy, coping, and a sense of coherence, as well as enhancing mindfulness.

Consistent effects across different populations, intervention forms and comparisons further enhance the relevance of the intervention. While MBSR clearly alleviated symptoms of stress and distress (and mental health more broadly defined), it also had effects on measures of personal development and quality of life. MBSR might be an attractive option for those interested in improving the way they cope with stress.

MBSR is group-based and can be delivered by non-medical personnel who have been given sufficient training and have experience in teaching and practising mindfulness.

6.2 IMPLICATIONS FOR RESEARCH

Further studies should explore ways to enhance the effects of MBSR interventions. To achieve this, qualitative design studies may prove to be valuable in gaining insight into participant perception and help to identify ways to involve participants more, thus strengthening the effects. However, when evaluating actual effects, RCTs must remain the preferred design; further uncontrolled studies are not needed. Longer follow-up periods are also required in order to assess and address long-term effects. Better reporting of randomised controlled trials is also urgently needed and future research should include head-to-head comparisons with other interventions. Well-designed primary studies ought to explore the effects of the length of the intervention as well as reported home practice. As this field rapidly evolves, we anticipate further combinations of both applied and basic approaches. Investigations of changes in brain and body functions may, for example, be embedded within trials. Such designs could potentially shed new light on mechanisms and interventions for change. New trials should include measures of mindfulness, preferably using the Five Facet Mindfulness Questionnaire (Baer,

2006). All trialists should attempt to share data, as many topics related to mechanisms may be explored in individual patient data meta-analyses.

7 Acknowledgements

The review draft was improved thanks to content and methods peer-reviewers, our English language consultant Simon Goudie, and the librarians Sølvi Biedilæ and Brynhildur Axelsdottir.

8 Differences between the protocol and the review

The use of the robust standard error approach in the analysis was not described in the protocol. This was because the method was published after the protocol had been accepted.

The suggested sensitivity analysis was processed using subgroup analysis (which relates to risks of bias and the application of ITT-analysis). We did not impute any missing information as attrition rates were low, and because neither risk of bias scores nor whether ITT-analysis was done, influenced the results.

Compliance was suggested both as a moderator and as part of the set of subgroup analyses. We chose the latter route.

Only seven studies measured mindfulness (in two different ways) and we chose not to perform the suggested moderator analysis.

With hindsight we should probably have avoided the mixture of concepts ´subgroup analysis´, ´moderator analysis´, and ´sensitivity analysis´. We had some real subgroups (e.g. clinical vs. non-clinical target groups), some study level variables (e.g. risk of bias) and variables on the individual level (e.g. compliance and self-reported practice). While it seemed meaningful to investigate heterogeneity in effects by means of subgroup analysis for the first two groups (as described in the main text), in our judgement the latter variables can be treated as moderators in a meaningful way only if access to individual patient data is possible.

9 Sources of support

This study is supported by The Norwegian Medical Association, The Norwegian Knowledge Centre for the Health Services, Centre for Child and Adolescent Mental Health, Eastern and Southern Norway, and SFI Campbell at The Danish National Centre for Social Research.

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11 Tables

11.1 CHARACTERISTICS OF INCLUDED STUDIES

Alterman 2004

Methods	**RCT**
Participants	Drug abusers in resident treatment for >2 months, Exclusion criteria: schizophrenia and borderline personality disorders, AIDS, hepatitis, regular mind-body practice in last two months
Interventions	MBSR vs. treatment-as-usual MBSR: 8 x 2 hours per week + 7 hour all-day session. 30-45 minutes of daily practice in a group
Outcomes	Semi-structured psychiatric interview measured problems in the following seven areas: medical, employment, alcohol, drug, legal, family-social and psychiatric. In addition, the following were also measured: spirituality, optimism, positive and negative mood, vitality, physical and mental health, drug and alcohol use, and meditation practice
Key conclusions	Addiction Severity Index indicated greater improvement in MBSR group in medical problems over a five month follow-up period, and a positive trend for psychological problems, but no other group differences and no difference in urine toxicology
Notes	Analysis by repeated measures of variance to look for group and time interactions. Because statistical power was low, effect sizes for group differences were also given

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number sequence
Allocation concealment	Unclear risk	Not specified

Bias	Authors' judgement	Support for judgement
(selection bias)		
Blinding (performance bias and detection bias)	High risk	University technicians administered interview at post-intervention and follow-up but not at baseline stage
Incomplete outcome data (attrition bias)	Low risk	Only three people dropped out of each group
Selective reporting (reporting bias)	High risk	No SD given
Other bias	High risk	Treatment staff administered interview at baseline, technical staff at other times

Anderson 2007

Methods	**RCT**
Participants	86 healthy adults
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, no all-day retreat
Outcomes	Attention control, depression, affect, anxiety, anger, rumination, worry, mindfulness and four attention tasks
Key conclusions	MBSR did not affect attentional control, but was associated with improvements ($p<0.01$) in emotional well-being (as measured by depression, anxiety, anger, positive affect, general rumination, anger rumination and anger sensitivity) and mindfulness. Changes in mindfulness predicted changes in emotional well-being in the MBSR group, and improved mindfulness enhanced awareness of present experience
Notes	Intention to treat (ITT) analysis not conducted as the number of dropouts in each group was equal (n=7). Greater negative affect, depression and anger rumination in MBSR group at baseline. Therefore multivariate ANOVA undertaken using baseline differences as covariates

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	The number of dropouts in each group was the same (n=7) hence the most conservative estimate of post-test scores would not have affected group mean differences post-test
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Astin 1997

Methods	RCT
Participants	Students
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, no all-day retreat
Outcomes	Psychological distress, control and spiritual experience
Key conclusions	MBSR significantly reduced psychological distress $p<0.002$, representing a 64% reduction in the MBSR group vs. 14 % in the control group. Increased overall sense of control ($p<0.02$), and use of more accepting/yielding mode of control $p<0.03$. Increase in measure of self as source of control $p<0.008$. Increased scores on the outcome of spiritual experiences $p<0.03$
Notes	Intention to treat (ITT) analysis not reported. ANOVA analysis was performed using change scores as dependent variable and baseline values as covariates. Wrote to author but further data unavailable

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation	Low risk	Coin flipping (confirmed after request for further information sent to author)

Bias	Authors' judgement	Support for judgement
(selection bias)		
Allocation concealment (selection bias)	Unclear risk	Person who did the coin flipping not specified
Blinding (performance bias and detection bias)	High risk	Most likely not blinded given that the researcher was acting as both instructor and data collector
Incomplete outcome data (attrition bias)	Unclear risk	Large dropout from control group
Selective reporting (reporting bias)	Unclear risk	Missing raw data from all facets of SCI (Sense Of Control Index)
Other bias	Low risk	No other bias detected

Bränström 2010

Methods	RCT
Participants	71 patients with varying cancer diagnoses who were not currently undergoing radiation or chemotherapy treatment
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, without all-day session
Outcomes	Stress, anxiety and depression, impact on event scale, mood states and mindfulness. Home-based meditation practice. All measured both before MBSR and one month after completion
Key conclusions	Significant decrease in stress, post-traumatic avoidance symptoms, and increased profile of mood states. Significant increase in mindfulness – this mediated the effects
Notes	Wrote to author who confirmed that the figures in Table 2 of the publication were generated using Intention to treat (ITT) analysis (32 persons in the MBSR group and 39 persons in the control group)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Software used for random selection procedure
Allocation concealment (selection	Low risk	

bias)		
Blinding (performance bias and detection bias)	Unclear risk	No blinding of group assignment
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis
Selective reporting (reporting bias)	Low risk	All reported, six month follow-up to be reported later
Other bias	Low risk	No other bias detected

Carson 2004

Methods	RCT
Participants	White couples either married or cohabitating >2 years, non-distressed (<58 on the global marital satisfaction inventory and <65 on the brief symptom inventory), not practising yoga or meditation regularly
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week + 7 hour all-day session, couple focus in the exercises
Outcomes	Global marital satisfaction inventory, brief symptom inventory, relationship satisfaction, autonomy, closeness, acceptance of partner, optimism, spirituality, individual relaxation index
Key conclusions	Favourable impact on relationship satisfaction, autonomy, relatedness, closeness, acceptance and relationship distress, same on individual optimism, spirituality, relaxation and distress, and results maintained at three months follow-up. Those who practised had better outcome
Notes	Sessions videotaped and rated for fidelity, daily practice diaries, experienced MBSR teachers

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not specified, randomisation stratified for couples

Allocation concealment (selection bias)	Unclear risk	Not specified, wrote to author
Blinding (performance bias and detection bias)	Unclear risk	Not specified,wrote to author
Incomplete outcome data (attrition bias)	Low risk	Equal dropout numbers in both groups, and differences between completers and dropouts analysed
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Cohen-Katz 2005

Methods	RCT
Participants	27 hospital staff, mainly nurses
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week + 6 hour all-day session
Outcomes	Burnout, distress and mindfulness
Key conclusions	Significant increase in mindfulness, significant decrease in emotional exhaustion (p=0.05) and increase in personal accomplishment (p=0.014). Trend for depersonalisation (p=0.063), but no significant difference in distress
Notes	More people with elevated distress in control group (7/13) than MBSR group (3/12) at pre-intervention

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias	Unclear risk	Not specified

and detection bias)		
Incomplete outcome data (attrition bias)	High risk	Missing data for the two dropouts in the intervention group not accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Large baseline difference in distress between intervention and treatment group not analysed

Creswell 2007

Methods	RCT
Participants	HIV-infected adults with psychological distress
Interventions	MBSR vs. 1-day MBSR control MBSR: 8 x 2 hours per week, 6-hour all-day session
Outcomes	Blood CD4+ T lymphocyte levels and concentrations of HIV-1 RNA
Key conclusions	MBSR can buffer CD4+ T lymphocyte declines in HIV-1 infected adults, independent of ARV (anti-retroviral) treatment status. Attendance predicted outcome and accounted for two-thirds of effect on CD4+T lymphocytes levels.
Notes	Intention to treat analysis conducted

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear sequence generation, reported use of "2:1 randomisation schedule"
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Low risk	Study assessment personnel were blinded to participant condition
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis conducted

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Davidson 2003

Methods	RCT
Participants	41 right-handed employees in a biotechnology corporation
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, 6-hour all-day session
Outcomes	Anxiety, positive and negative affect, EEG brain changes, antibody titre after influenza vaccination
Key conclusions	Significant increase in left-sided anterior cortical activation in EEGs of MBSR group members, and significant increase in antibody titre rise. Magnitude of cortical change predicted magnitude of antibody response
Notes	Insufficient reporting on psychometric data

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	Data on anxiety outcome for T3 is missing
Other bias	Unclear risk	Possible contamination as all participants came from same firm

de Veer 2009

Methods	RCT matched for age, gender and education
Participants	46 persons enrolled. Programme completed by 37 persons who stutter (29 males and 8 females)
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week
Outcomes	Stress, anxiety about speech situations, self-efficacy, coping, locus of control, and attitude towards speech situations
Key conclusions	MBSR group showed reduced suffering from stress and related tension and fatigue, reduced anxiety about speech situations and more confidence in approaching speech situations. MBSR group felt more in control and used more problem-focussed coping
Notes	Follow-up data cannot be used in meta-analysis because follow-up done in parallel with the wait-list group receiving MBSR. Wrote to author and received additional information. Attendance recorded, but not duration of practice time

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Done by main experimenter using coin flipping
Allocation concealment (selection bias)	High risk	
Blinding (performance bias and detection bias)	Low risk	Questionnaires received anonymously in sealed envelopes by second investigator
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	All outcomes addressed
Other bias	High risk	Did not use intention to treat analysis; no analysis of dropouts

de Vibe 2006

Methods	RCT
Participants	144 people with stress and chronic illnesses
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session

Outcomes	Psychological distress, subjective health complaints, and quality of life
Key conclusions	MBSR group showed reduced distress and health complaints and increased quality of life. Significant effect of amount of practice on quality of life measures at follow-up. Same trend on subjective health complaints
Notes	Follow-up after crossover of wait-list control group who then received MBSR. Same results as the intervention group after 6 months follow-up. Follow-up results therefore not included in our analyses

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used dice
Allocation concealment (selection bias)	High risk	Allocation done by main investigator
Blinding (performance bias and detection bias)	High risk	Data collected by main investigator
Incomplete outcome data (attrition bias)	Low risk	No dropouts in control group, 10% dropout in intervention group accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Baseline data gathered at inclusion to study, but groups started at different times after inclusion

Grossman 2010

Methods	RCT, randomised in blocks of 4-6
Participants	150 patients with mild to moderate multiple sclerosis
Interventions	MBSR vs. usual care MBSR: 8 weeks x 2.5 hours per week, 7-hour all-day session
Outcomes	Quality of life, depression, fatigue and anxiety
Key conclusions	Significant decrease on all effect parameters, but not on disease-specific function of limbs noted at post-intervention and 6 months later. A lessening of effect at 6 months follow-up but still significant. When groups with depression, fatigue and anxiety at pre-intervention (using clinical cut-off points) were analysed separately, considerably higher effect sizes were

	found, indicating a floor effect. Improvements in quality of life, depression and anxiety correlated with practice
Notes	High compliance and attendance, and low attrition in MBSR group. Intention to treat (ITT) analysis

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation using random event generator
Allocation concealment (selection bias)	Low risk	Done by principal investigator who was blinded to all patient information
Blinding (performance bias and detection bias)	Low risk	Outcome measures entered into database by personnel blinded to group assignment
Incomplete outcome data (attrition bias)	Low risk	All outcomes addressed
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	No other bias detected

Jain 2007

Methods	RCT
Participants	104 healthcare/medical students
Interventions	MBSR vs. waiting-list control vs. relaxation training MBSR: 4 x 1.5 hours per week, 6-hour all-day session
Outcomes	Mental distress, positive mood, distraction, rumination and spiritual experiences
Key conclusions	Both MBSR and relaxation training reduced psychological distress and increased positive mood, but MBSR reduced distractive and ruminative thoughts and behaviours and the effect on distress was mediated through this. No effect noted on spiritual experiences. Effect of practice duration on outcome for distress and positive mood
Notes	Intention to treat (ITT) analysis performed

Risk of bias table

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Computer program used to stratify participants for sex and student status
Allocation concealment (selection bias)	Low risk	Computerised generation
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	All outcomes addressed
Selective reporting (reporting bias)	Low risk	Intention to treat (ITT) analysis performed
Other bias	Low risk	No other bias detected

Klatt 2009

Methods	RCT
Participants	48 university faculty and staff
Interventions	MBSR vs. wait-list control MBSR: 6 x 1 hour per week, 20 minutes of home practice
Outcomes	Stress, sleep, mindfulness, salivary cortisol
Key conclusions	The MBSR group experienced significant stress reduction and an increase in mindfulness, despite receiving a short MBSR course. No effect on salivary cortisol
Notes	Intention to treat (ITT) analysis not reported

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	MBSR group data was collected at MBSR meetings
Incomplete outcome data (attrition	Low risk	Small amount of missing data

Bias	Authors' judgement	Support for judgement
bias)		
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Koszycki 2007

Methods	RCT
Participants	58 patients with generalised social anxiety
Interventions	MBSR vs. GBCT (12-week group based cognitive therapy) vs. control MBSR: 8 x 2.5 hours per week, 7.5-hour all-day session
Outcomes	Anxiety, illness severity, social interaction and interpersonal sensitivity, self-rated disability, depression, quality of life
Key conclusions	Patients receiving both MBSR and GBCT improved, but those who received GBCT had greater effects on social anxiety, and equal effects in terms of improving mood, functionality, and quality of life compared to the MBSR group.
Notes	For those with serious problems, a 12-week intervention was too short

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Low risk	Assessors on clinician-rated instruments blinded
Incomplete outcome data (attrition bias)	Low risk	Two analyses performed: Intention to treat (ITT) analysis, and analysis of completer sample (including patients who completed and attended at least 80% of the sessions). Expectation maximisation method used to impute missing values
Selective reporting	Low risk	All outcomes reported

(reporting bias)		
Other bias	Low risk	No other bias detected

Lengacher 2009

Methods	RCT
Participants	84 women over 21-years of age diagnosed with breast cancer Stage 0-III who had undergone surgery and received adjuvant radiation and/or chemotherapy and had completed their treatment within the last ten months
Interventions	MBSR vs. wait-list control MBSR: 6 x 2 hour sessions per week, adapted for breast cancer survivors. Attendance and home practice measured. 70% considered compliant, one of the seven groups received only five sessions due to the occurrence of a tropical storm
Outcomes	Concerns about recurrence, anxiety, depression, life orientation, stress, spirituality, symptoms
Key conclusions	MBSR sign improved psychological distress, fear of recurrence and QOL. Extent of practice influences overall benefit. Attendance alone showed a favourable effect on psychological status
Notes	Adjusted means given, wrote to author to obtain unadjusted means and SD values. Symptoms measured by the MDASI – not reported in study

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	High risk	Outcome assessors not blinded to follow-up from baseline
Incomplete outcome data (attrition bias)	Low risk	One dropout from each group, unlikely to introduce bias
Selective reporting (reporting bias)	Unclear risk	They mention that they did not report symptoms from the MDASI, but not why

Other bias	Unclear risk	Did not use correction for large numbers of outcomes

Moritz 2006

Methods	RCT
Participants	165 people with emotional distress measured using the Profile of Mood States (POMS)
Interventions	MBSR vs. home-based spirituality programme (8 x 1.5 hours audiotape sessions per week + daily 45-minute audiotape practice) vs. wait-list control MBSR: 8 x 1.5 hours per week, daily 45-minute audiotape practice
Outcomes	Profile of mood state and health-related quality of life
Key conclusions	At post-intervention, significant effect of both interventions: significantly more for spirituality group than MBSR group. Post-intervention effect of MBSR maintained at four weeks, where both interventions' effects were equal but still significantly different from those in the wait-list group
Notes	Baseline differences (not significant) with more mental distress in spirituality group. Adherence and practice greater in spiritual group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program used
Allocation concealment (selection bias)	Low risk	Done by biostatistician. Allocation list available only to an administrator who was not involved in the study
Blinding (performance bias and detection bias)	Low risk	All data collection forms mailed out and returned by post
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis performed
Selective reporting (reporting bias)	Unclear risk	Subscale scores for SF36 at four weeks post-intervention not reported
Other bias	Low risk	No other bias detected

Morone 2008

Methods	RCT

Participants	37 participants with chronic lower back pain, aged >65 years
Interventions	MBSR vs. wait-list control MBSR: 8 x 1.5 hours per week
Outcomes	Pain and pain acceptance, physical function, physical health, global health and mental health
Key conclusions	Significant improvement in pain acceptance, and physical function
Notes	Follow-up after crossover of control group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program used
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes
Blinding (performance bias and detection bias)	Low risk	Outcome assessor masked to group assignment
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis method with last value carried forward
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Murphy 1995

Methods	RCT
Participants	31 male inmates with a history of alcohol abuse and aggression
Interventions	MBSR vs. progressive relaxation training (PRT: 6 x 2-hour sessions held over 5-week period) MBSR: 6 x 2 hours held over 5-week period
Outcomes	Egocentrism, anger, impulsivity and stress reactivity by measuring saliva cortisol after stress test
Key conclusions	Small reductions in self-reported anger in both groups. No change in impulsivity. Significant within-group post-stressor reduction in cortisol in PRT

	group. A significant between-group difference favouring MBSR intervention on sub-measure of egocentrism (called negative self-focussed attention). At one-month follow-up, a slight decrease in aggressive response in MBSR group and a slight increase in PRT group
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Murray 2004

Methods	RCT
Participants	27 male students using sex as a coping strategy
Interventions	MBSR vs. wait list control MBSR: 8 x 1.5 hours per week
Outcomes	Coping using sex strategies, regulation of negative affect, general mood
Key conclusions	MBSR increased effectiveness of handling negative mood states, and decreased avoidant coping strategies, but did not alter approach coping strategies
Notes	Intention to treat analysis not conducted

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment	Unclear risk	Not specified

(selection bias)		
Blinding (performance bias and detection bias)	High risk	Partly: research assistant collected majority of data but PANAS was collected by co-therapist
Incomplete outcome data (attrition bias)	High risk	Equal numbers of dropout from each group, reasons for dropout addressed
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Nyklicek 2008

Methods	RCT
Participants	60 people experiencing regular distress
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session, 40-minute home practice
Outcomes	Perceived stress, exhaustion, positive and negative affect, quality of life, mindfulness
Key conclusions	MBSR decreased distress, exhaustion and negative affect. MBSR increased QoL to a lesser extent. Changes partially mediated by increase in measured mindfulness
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program used
Allocation concealment (selection bias)	Low risk	Allocators were blinded
Blinding (performance bias and detection bias)	Low risk	Questionnaires sent to participants
Incomplete outcome data (attrition bias)	Low risk	Last values carried forward
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Oman 2008

Methods	RCT
Participants	54 undergraduate college students
Interventions	MBSR vs. EPP (Easwaran's Eight-Point Programme – 8 x 1.5 hours per week) vs. wait-list control MBSR: 8 x 1.5 hours per week
Outcomes	Perceived stress, rumination, forgiveness of others, hope
Key conclusions	MBSR and EPP had the same significant effect on stress, forgiveness and the same trend on reducing rumination. No effect on hope
Notes	Authors state that they did perform intention to treat (ITT) analysis, but not all randomised participants included (only 44)

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer program used
Allocation concealment (selection bias)	Low risk	Computer program used
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Reported that four dropouts were not significantly associated with pre-test values or covariates on any outcome
Selective reporting (reporting bias)	Low risk	No other bias detected
Other bias	High risk	EPP and MBSR groups analysed together. 5 participants crossed over between intervention and control groups after randomisation

Plews-Ogan 2005

Methods	RCT
Participants	30 patients with chronic musculoskeletal pain
Interventions	MBSR vs. massage (one hour a week for 8-week period) vs. treatment as usual MBSR: 8 x 2.5 hours per week

Outcomes	Pain sensation, pain unpleasantness, global physical and mental health
Key conclusions	Massage group showed an effect on pain and mental health after intervention but not at follow-up. MBSR had no effect on pain outcomes, but had significant effect on mental health at follow-up
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number sequence used
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	High risk	Not reported
Incomplete outcome data (attrition bias)	High risk	Incomplete data on dropouts in MBSR group
Selective reporting (reporting bias)	High risk	Incomplete outcome data on physical health and pain sensation
Other bias	Low risk	No other bias detected

Pradhan 2007

Methods	RCT
Participants	63 rheumatoid arthritis patients not in remission
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session. Three refresher classes in the follow-up period
Outcomes	Psychological distress, depression, well-being, disease activity, mindfulness
Key conclusions	No significant results after intervention, but significant reduction in distress and increased well-being and mindfulness at follow-up at four months
Notes	Post-intervention and frequency of practice (but not time spent) were related to outcome, but not at six months follow-up. Better results obtained with one of the three instructors involved (who was also the most experienced)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Conducted by research director who had no direct patient contact (using Mienert clinical trials assignment procedure)
Blinding (performance bias and detection bias)	Low risk	All rheumatoid arthritis disease activity assessors and lab personnel blinded
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis using all available data. Last value carried forward to impute missing data Results for imputed and non-imputed data were reported as similar; final analyses based on non-imputed data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Robert-McComb 2004

Methods	RCT
Participants	20 women with cardiovascular disease
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week
Outcomes	Physical health, catecholamines, cortisol, breathing rate, oxygen consumption, tidal volume, and heart rate
Key conclusions	Significant effect on breathing pattern with increased ventilatory efficiency during exercise. No effect on hormone resting levels
Notes	Data from study first published by Tacon in 2002

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection	Unclear risk	Random selection with number 1 & 2 but unclear how it was done

Bias	Authors' judgement	Support for judgement
bias)		
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Only two dropouts, one from each group
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Sephton 2007

Methods	RCT
Participants	91 women with fibromyalgia
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session
Outcomes	Functional impairment, pain, sleep, depression
Key conclusions	MBSR alleviated symptoms of depression in fibromyalgia patients and reduced somatic symptom scores. Participants who meditated experienced greatest reduction in depressive symptoms at the end of the study ($p<.05$). Attendance had no significant effect on outcome
Notes	Follow-up immediately after intervention and after two months. Attendance 69%. 87.5% meditated regularly at post-intervention and 73% at two months follow-up

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment	Unclear risk	Not specified

(selection bias)		
Blinding (performance bias and detection bias)	Low risk	Data entry personnel blinded
Incomplete outcome data (attrition bias)	Low risk	Two analyses performed. In one, the last observation was carried forward and used for missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Shapiro 1998b

Methods	RCT (confirmed by author)
Participants	78 medical and pre-medical students
Interventions	MBSR vs. wait-list control MBSR: 7 x 2.5 hours per week
Outcomes	Empathy, psychological distress, depression, anxiety and spirituality
Key conclusions	MBSR group experienced reduced state and trait anxiety, distress and depression, increased empathy and spiritual experiences. Result replicated in wait-list control group, by different experimenters. Results measured at student exam time
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Low risk	Outcome assessor masked to group assignment
Incomplete outcome data (attrition bias)	Unclear risk	Large number of dropouts in MBSR group

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Shapiro 2005

Methods	RCT
Participants	38 healthcare professionals
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week
Outcomes	Psychological distress, burnout, perceived stress, life satisfaction, self-compassion
Key conclusions	MBSR group reported decreased perceived stress and greater self-compassion compared to control group. Changes in self-compassion significantly predicted positive changes in perceived stress but not changes in satisfaction with life
Notes	Intention to treat (ITT) analysis not conducted, significant dropout (44%) in intervention group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	Data collected by research assistant and also by co-therapist
Incomplete outcome data (attrition bias)	Unclear risk	Large dropout rate, no intention to treat (ITT) analysis
Selective reporting (reporting bias)	Unclear risk	All outcomes reported
Other bias	Unclear risk	No other bias detected

Speca 2000

Methods	RCT

Participants	109 cancer patients
Interventions	MBSR vs. wait-list control MBSR: 7 x 1.5 hours per week
Outcomes	Mood disturbance, physical, psychological and behavioural response to stress
Key conclusions	MBSR had a significant effect on all outcome measures
Notes	Those who dropped out had greater baseline anxiety and depression. The best predictor of improvement was the number of sessions attended (this explained 13.2% of the variance)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Fixed randomisation scheme using a table of random numbers
Allocation concealment (selection bias)	Low risk	Allocation concealed by using numbers to identify participants. The investigator did not know the association between the individual participants and the numbers used to identify them
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analyses for dropouts imputed; last value carried over. Value entered as '0'
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Surawy 2005

Methods	RCT
Participants	18 patients with chronic fatigue syndrome (CFS)
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week
Outcomes	Anxiety and depression, fatigue, physical function
Key conclusions	Significant effect of MBSR on reducing anxiety and fatigue, but no effect on

	depression or physical function
Notes	Baseline differences not accounted for in the analysis

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Only one lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Before study inclusion, study population had attended varying numbers of psychiatric sessions. Baseline differences not accounted for in the analysis

Tacon 2003b

Methods	RCT
Participants	20 women with cardiovascular disease
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week
Outcomes	Anxiety, emotional control, coping, health locus of control, health-related quality of life, cortisol, submaximal exercise response
Key conclusions	Significant effect on anxiety, emotional control and reactive coping. Significant effect on breathing pattern with increased ventilatory efficiency during exercise. No effect on hormone resting levels
Notes	Data from exercise tests and hormone measurements published in separate article by Robert-McComb in 2004

Risk of bias table

Bias	Authors'	Support for judgement

	judgement	
Random sequence generation (selection bias)	Unclear risk	Random selection using numbers 1 & 2, unclear how this was done
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Only two dropouts, one from each group
Selective reporting (reporting bias)	High risk	Relevant outcome data not provided for non-significant outcomes
Other bias	Low risk	No other bias detected

Vieten 2008

Methods	RCT
Participants	34 pregnant women experiencing mood problems
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, exercises adapted to suit pregnant women
Outcomes	Stress, anxiety, affect, affect regulation, mindfulness
Key conclusions	Mindfulness training during pregnancy may significantly reduce anxiety and negative affect
Notes	Intention to treat (ITT) analysis not reported

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and	Unclear risk	Not specified

detection bias)		
Incomplete outcome data (attrition bias)	Low risk	Small amounts of missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Large imbalance at baseline, but adjusted for by using ANCOVA analysis

Weissbecker 2002

Methods	MBSR
Participants	91 women with fibromyalgia
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week
Outcomes	Sense of coherence (SOC), fibromyalgia symptom impact, perceived stress and depression
Key conclusions	Significant increase in SOC in MBSR group, correlated to degree of attendance. A higher level of SOC was significantly related to less distress and depression, but SOC did not buffer for the negative effects of fibromyalgia symptoms on psychological distress (as analysed using hierarchical regression)
Notes	Only full data on SOC variable supplied; same study as Sephton published in 2007

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Tested for differential attrition; showed no significant differences between treatment and control groups
Selective reporting (reporting	Unclear risk	Full data on perceived stress and depression not

Bias	Authors' judgement	Support for judgement
bias)		provided
Other bias	Low risk	No other bias detected

Williams 2001

Methods	RCT
Participants	103 community volunteers who were stressed
Interventions	MBSR vs. treatment-as-usual control (also given unspecified educational material) MBSR: 8 x 2.5 hours per week, 8-hour all-day session
Outcomes	Daily stress, distress and medical symptoms
Key conclusions	MBSR group showed significant reduction in stress, distress, and medical symptoms
Notes	Used a stress map inventory and action plan workbook in the MBSR classes

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	ITT reported
Selective reporting (reporting bias)	Low risk	Note all outcome data reported
Other bias	Low risk	No other bias detected

11.2 CHARACTERISTICS OF EXCLUDED STUDIES

Study	Reason for Exclusion
Abbey 2003	Not an RCT
Abbott 2006	Unobtainable
Alexander 1989	Not MBSR
Allen 2006	Not a primary study
Alterman 2004	Not an RCT
American 2007	Not a primary study
Arias 2006	Not a primary study
Arnold 2001	Not a primary study
Arthur 2006	Not a primary study
Astin 2003a	Measures effect of MBSR in combination with Qi-Gong
Astin 2003b	Not a primary study
Astin 2004	Not a primary study
Bahrke 1978	Not MBSR
Barrows 2002	Not a primary study
Berking 2007	Not a primary study
Biegel 2009	Not an RCT
Bishop 2002	Not a primary study
Boerstler 1987	Not a primary study
Brach 1992	Not MBSR
Brandon, 1985	Not MBSR
Brazier 2006	Not MBSR
Britton 2007	Unobtainable, author contacted
Bruckstein 1999	Not an RCT. Participants themselves could choose which group to participate in.
Bruning 1987	Not MBSR
Butler 2006	Not MBSR
Bögels 2008	Not an RCT

Study	Reason for Exclusion
Carson 2006	Not a primary study
Chang 2003	Not MBSR
Cohen-Katz 2004	Not a primary study
Coulter 2002	Not a primary study
Davies 2008	Not a primary study
Deepak, 1994	Not MBSR
Delmonte 1985	Not a primary study
Delmonte 1990	Not a primary study
Diamond 1987	Not a primary study
Dosh 2002	Not a primary study
Ebell 2001	Not a primary study
Edwards 2003	Not a primary study
Ernst 2008	Not an RCT
Ferren 2004	Not an RCT
Fjorback 2008	Not a primary study
Flanzbaum 2003	Not an MBSR
Foley 2006	Unobtainable
Galantino 2005	Not an RCT
Garland 2007	Not an RCT
Garland 2010	Not an RCT
Gaston 1991	Not MBSR
Gazella 2005	Not a primary study
Goodman 2004	Primary study reported in Plews-Ogan (2005)
Greene 1988	Not MBSR
Grossman 2004	Not a primary study
Grossman 2007	Not an RCT
Hall 1999	Not MBSR
Hart 2007	Not a primary study
Hassed 2004	Not MBSR

Study	Reason for Exclusion
Haynes 2007	Unobtainable
Health & Medicine 2008	Not an RCT
Hebert 2001a	Not MBSR: several sessions lead by psychiatrist which addressed issues of coping with breast cancer
Hellman 1990	Not MBSR
Hildenbrand 1986	Not a primary study
Hodges 2000	Not a primary study
Horrigan 2006	Not a primary study
Horrigan 2007	Not a primary study
Horton-Deutsch 2003	Not a primary study
Horton-Deutsch 2007	Not an RCT
Humphrey 1999	Not MBSR
Issel 2007a	Not a primary study
Issel 2007b	Not an RCT
Ivanovski 2007	Not a primary study
Jackson 2004	Unpublished, unobtainable
Jacobs 2003	Not an RCT
Jaltuch 1997	Unobtainable
Jha 2007	Not an RCT
Johnson 2004	Not MBSR
Kabat-Zinn 1985	Not an RCT
Kabat-Zinn 1986	Unobtainable
Kabat-Zinn 1992	Not an RCT
Kabat-Zinn 1998	Not MBSR (used only audiotapes)
Kindlon 1983	Not MBSR
Koerbel 2007	Not a primary study
Krisanaprakornkit 2006	Not a primary study
Krisanaprakornkit 2007	Not a primary study
Kroese 2005	Not a primary study
Kron 2004	Not a primary study

Study	Reason for Exclusion
Kron 2007	Not a primary study
Lee 2007	Not MBSR
Linden 2001	Not an RCT
Loganathan 2007	Not MBSR
Lombart 1998	Not an RCT
Lundh 2005	Not a primary study
Luskin 2000	Not a primary study
Lynch 2004	Not an RCT
Mackenzie 2006	Not an RCT
Manzoni 2008	Not a primary study
Maras 1984	Not an RCT
Marcus 2001	Not an RCT
Marcus 2007	Not an RCT
Massion 1997	Unobtainable
Matchim 2007	Not a primary study
McCarberg 1999	Not MBSR
McMillan 2002	Not MBSR
Medical Devices 2008	Not an RCT
Melnyk 2005	Not a primary study
Michalak 2006	Not a primary study
Michalsen 2002	Not an RCT
Moghaddam 2007	Not MBSR
Monk-Turner 2003	Not an RCT
Monti 2005	Not MBSR: the art therapy component went beyond standard forms of MBSR intervention and was not simply an adaptation
Morone	Primary study reported in Morone 2008
Morone 2006	Primary study reported in Morone 2008
Morone 2007	Not a primary study
Mulligan 2004	Not a primary study
Murphy 1986	Not MBSR

Study	Reason for Exclusion
Murphy 1996	Not a primary study
Napoli 2005	Not MBSR
Neale 2007	Not a primary study
Nielsen 2006	Not an RCT
Ormrod 1991	Not MBSR
Ortner 2007	Not MBSR
Ott 2006	Not a primary study
Ozcelik 2007	Unobtainable
Palmkron 2008	Not a primary study
Papp 2001	Not a primary study
Paradies 2006	Not a primary study
Patel 1985	Not MBSR
Paterniti 2008	Not an RCT
Pauzano-Slamm 2005	Not an RCT
Pearl 1994	Not an RCT
Perkins 1998	Combination of MBSR and progressive relaxation
Phelps 2005	Unobtainable
Poulin 2005	Not an RCT
Poulin 2008	Not an RCT
Praissman 2008	Not a primary study
Proulx 2003	Not a primary study
Rainforth 2007	Not a primary study
Ramel 2004	Not an RCT
Randolph 1999	Not an RCT
Rhead 1983	Not an RCT
Robinson 2003	Not an RCT
Rosdahl 2003	Not an RCT
Rosenzweig 2003	Not an RCT
Roth 2004	Not an RCT

Study	Reason for Exclusion
Sagula 2004	Not an RCT
Salmon 2004	Not a primary study
Saxe 2001	Not an RCT
Schmidt 2008	Not an RCT
Schure 2008	Not an RCT
Severtsen 1986	Not MBSR
Shapiro 1998a	Primary study reported in Shapiro 1998b
Shapiro 2002	Unobtainable
Shapiro 2003	Quasi-experimental due to pre-intervention measures being given after randomisation; the two treatment options were not equivalent and affected answers to pre-intervention protocol
Shapiro 2007	Not an RCT
Shigaki 2006	Not a primary study
Singh 2002	Not an RCT
Singh 2004	Not an RCT
Singh 2006a	Not an RCT
Singh 2006b	Not an RCT
Smith 2004	Not a primary study
Smith 2005a	Not a primary study
Smith 2005b	Unobtainable
Smith 2007	Unobtainable
Smith 2008	Not an RCT
Snaith 1998	Not a primary study
Solloway 2007	Not an RCT
Soskis 1989	Not an RCT
Spanos 1980	Not an RCT
Spence 2006	Not MBSR
Starks 2007	Unobtainable
Stauffer 2008	Not an RCT
Tacon 2003a	Not a primary study

Study	Reason for Exclusion
Tacon 2004	Not an RCT
Tate 1994	Not an RCT
Toneatto 2007	Not a primary study
Tremblay 2008	Not a primary study
von Weiss 2002	Not a primary study
Walach 2007	Not an RCT
Weiss 2005	Not an RCT
Wilson 2000	Unobtainable
Winbush 2007	Not a primary study
Åsberg 2006	Not a primary study

11.3 STUDY CHARACTERISTICS

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
Alterman 04	Substance abusers	ASI, SF-36-Vit, SF-36 Ph, SF-36 Me, SAS, LOT, LAP-R, PANAS-Pos	31	3	23			Non-ITT
Anderson 07	General	BAI, Anx Sens I, BDI, TMS, Anger Rum S, N Anger I, RSQ, PANAS, Penn State Worry	86		16	18	65	Non-ITT
Astin 97	Students	INSPIRIT, SCI, GSI	28		16	18		Non-ITT
Bränström 10	Cancer	HADS, FFMS,PSOM, PSS, IES-R	85		16		73	ITT
Carson 04	Ordinary couples	IRI, LOT, INSPIRIT,GSI	114	3	27	32	80	Non-ITT
Cohen-Katz 05	General	MAAS, MBI	27		26			Non-ITT
Creswell 08	HIV positive	CD4+T lymphocytes	67		22		57	Non-ITT
Davidson 03	General	STAI Trait, AB titre	41		26	7		Non-ITT
de Veer 09	People with stutter	SSC, SESAS, PSI, LCB, PSS, S-24	46		20		80	Non-ITT
de Vibe 06	Chronic illness and stress	WHOQOL-BREF, SCL-5, SHC	144		26		81	Non-ITT

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
Grossman 10	Multiple sclerosis	STAI, CES-D, HAQUAMS, PQOLC, MFIS fatigue	150	6	27	30	92	ITT
Jain 07	Students	DER, INSPIRIT, PSOM, GSI	69		12	45		Non-ITT
Klatt 09	University staff	GI SleepQ, PSS, MAAS	48		6	17	80	Non-ITT
Koszycki 07	Social anxiety	LSAS, CGI, SIAS, SPS, IPSM, LSRDS, BDI, QoLI	53		28		94	ITT
Lengacher 09	Cancer	STAI, CES-D, LOT, PSS, SF36 PhyS, SF36 MentalS	84		12	30	80	ITT
Moritz 06	Distress	POMS, SF36 PhyS, SF36 MentalS	109	1	12	18	65	ITT
Morone 08	Chronic low back pain	CPAQ, McGPQ, SF-36	37		12	32	84	Non-ITT
Murphy 95	Prisoners	STAXI, Egocentricity, salivary cortisol	31		12			Non-ITT
Murrey 04	Students	CUSI, CSI, NMRS, PANAS	27		12	35		Non-ITT
Nyclicek 08	Distress	WHOQOL-BREF, MAAS, PANAS, PSS, MQ	60		26			ITT
Oman 08	Students	PSS, RRQ, H Forgiveness S, ADHS	31	2	12		83	Non-ITT
Plews-Ogan 05	Chronic muscular-	SF-12 mentalS, PUS	20	1	20		79	Non-ITT

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
	skeletal pain							
Pradhan 07	Rheumatoid arthritis	SCL-90 dep, MAAS, PWS, GSI, DAS28	63	4	26	8	85	ITT
Sephton 07	Fibromyalgia	BDI, SOC	91	2	26		69	ITT
Shapiro 05	Health professionals	MBI, SCS, PSS, SWLS	38		16			Non-ITT
Shapiro 98	Students	STAI, SCL-90 depr, ECRS, INSPIRIT, GSI	78		18			Non-ITT
Speca 00	Cancer	POMS, SOSI	109		11		85	ITT
Surawy 05	Chronic fatigue syndrome	HADS, CFS, SF-36	18		20		75	Non-ITT
Tacon 03	Cardiovascular disorder	STAI , CECS, PF-SOC, Catecholamines, Cortisol, SF-36, HR, TV, Vent	20		16			Non-ITT
Vieten 08	Mood disturbance	STAI, CES-D, MAAS, ARM, PANAS, PSS	34		16	11	90	Non-ITT
Williams 01	Stress	Daily Stress I, GSI, MSCL	103	3	28		83	Non-ITT

Total number randomised: 1,942

11.4 MEASUREMENT SCALES, ABBREVATIONS

Measurement Scales, Abbreviations
AB titre=Influenza Antibody Titre
Anger Rum S=Anger Rumination Scale
Anx Sens I=Anxiety Sensitivity Index
ARM=Affect Regulation Measure
ASI=Addiction Severity Index
BAI=Beck Anxiety Index
BDI=Beck Depression Inventory
CECS=Courtauld Emotional Control Scale
CES-D=Centre for Epidemiologic Studies Depression Scale
CFS=Chalder Fatigue Scale
CGI=Clinical Global Impression
CPAQ=Chronic Pain Acceptance Questionnaire
CSI=Coping Strategi Index
CUSI=Coping Using Sex Inventory
DAS28=Disease Activity Scale
DER=Daily Emotion Report
DSI=Daily Stress Inventory
ECRS=Empathy Construct Rating Scale
FFMS=Five Facet Mindfulness Scale
GI SleepQ=Pittsburgh Sleep Quality Index
GSI=General Severity Index from the Hopkins Symptom Checklist-90
HADS=Hospital Anxiety and Depression Scale
HAQUAMS=Hamburg Quality of Life Questionnaire in Multiple Sclerosis
HFS=Heartland Forgiveness Scale
HR=Heart Rate
IES-R=Impact of Event Scale-Revised (sub-scales for intrusion, avoidance and hyperarousal)
INSPIRIT=Index of Core Spiritual Experience

Measurement Scales, Abbreviations
IPSM=Interpersonal
IRI=Individual Relaxation Index
ITT= Intention to treat analysis
LAP-R=Reker's Life Attitude Profile-Revised
LCB=Locus of Control of Behaviour Scale
LOT=Life Orientation Test
LSAS=Liebowitz Social Anxiety Scale (Fear and Avoidance sub-scales)
LSRDS=Liebowitz Self-Rated Disability Scale
MAAS=Mindfulness Attention Awareness Scale
MBI= Maslach Burnout Inventory (sub-scales for Emotional Exhaustion, Depersonalization and Personal Accomplishment)
McGPQ=McGill Pain Questionnaire Short Form
MBSR=Mindfulness Based Stress Reduction
MQ=Maastrict Questionnaire
MSCL=Medical Symptom Checklist
N Anger I=Novaco Anger Inventory
NMRS=Negative Mood Regulation Scale
PANAS-Pos=Positive and Negative Affect Scale – Positive
PF-SOC=Problem-Focused Styles of Coping
POMS=Profile of Mood States Scale
PQOLC=Profile of Health-Related Quality of Life in Chronic Disorders
PSI=Perceptions of Stuttering Inventory
PSOM=Positive States of Mind
PSS=Perceived Stress Scale
P State Worry=Penn State Worry
PUS=Pain Unpleasantness Scale
PWS=Positive Well-Being Scales
QoLI=Quality of Life Inventory
Vital Exhaustion,
RRQ= Rumination and Reflection Questionnaire

Measurement Scales, Abbreviations
RSQ=Rumination Scale of the Response Styles Questionnaire
S-24=Attitude towards speech situations
SAS=Hovden Spirituality Assessment Scale
SCI=Shapiro Control Index
SCL-5=Hopkins Symptom Checklist-5
SCL-90 dep=Hopkins Symptom Checklist 90 Depression sub-scale
SCS=Self-Compassion Scale
Sensitivity Measure,
SESAS=Self-Efficacy Scale for Adults who Stutter
SF-12 mentalS=Health Survey Questionnaire-Mental summary score
SF36 PhysS=Health Survey Questionnaire – Physical Summary Score
SF36 mentalS=Health Survey Questionnaire – Mental Summary Score
SF-36-Vit=Health Survey Questionnaire-Vitality sub-scale
SHC=Ursin Subjective Health Complaints
SIAS=Social Interaction Scale
SOC=Sense of Coherence
SOSI=Symptoms of Stress Inventory
SPS=Social Phobia Scale
SSC=Speech Situation Checklist
STAI Trait=Spielberger State-Trait Anxiety Inventory
SWLS=Satisfaction With Life Scale
TV=Tidal Volume
Vent=Ventilation,
WHOQOL-BREF= World Health Organization Quality of Life Scale Brief version

11.5 EFFECT SIZES AND OUTCOMES

Outcomes	Studies	Measurement scales (some scales reported outcomes using many subscales)	Hedges' g-values	95% CI	Heterogeneity
Anxiety (10 studies, 12 outcomes)	Anderson, Bränstöm, Davidson, de Veer, Grossman, Langacher, Shapiro 98, Surawy, Tacon, Vieten	BAI, HADS, Anxiety about speech, STAI trait, STAI state	0.53	0.43-0.63	Tau^2: 0.0 I^2: 0%
Depression (9 studies, 9 outcomes)	Anderson, Bränstöm, Grossman, Langacher, Pradhan, Sephton, Shapiro 98, Surawy, Vieten	BDI, HADS, CES-D, SCL90-D	0.54	0.35-0.74	Tau^2: 0.03 I^2: 32%
Stress/distress (20 studies, 28 outcomes)	Astin, Bränstöm, Carson, Cohen-Katz, de Veer, de Vibe, Grossman, Jain, Klatt, Langacher, Moritz, Morone, Nyklicek, Plews-Ogan, Pradhan, Shapiro 98, Shapiro 05, Speca, Vieten, Williams	GSI, PSS, MBI, SCL-5, MFIS-F, SF36-M, Vital exh, SOSI, DSI	0.56	0.44-0.67	Tau^2: 0.009 I^2: 11%
Other measures of mental health (12 studies, 30 outcomes)	Anderson, Astin, Bränstöm, Carson, de Veer, Jain, Klatt, Langacher, Moritz, Nyklicek, Speca, Vieten, Williams	Anx Sens I, Anger Rum S, N Anger I, PANAS, P State Worry, RSQ, IES-R, IRI, LOT, S-24, SESAS, DER, GI SleepQ, POMS, ARM	0.48	0.34-0.61	Tau^2: 0.0 I^2: 0%
Mental health	All studies	All of Anxiety, Depression, Stress and Other	0.53	0.46-0.61	Tau^2: 0

Outcomes	Studies	Measurement scales (some scales reported outcomes using many subscales)	Hedges' g-values	95% CI	Heterogeneity
(26 studies, 79 outcomes)		mental health outcomes			I^2: 0%
Personal development (12 studies, 21 outcomes)	Astin, Bränstöm, Carson, de Veer, Jain, Morone, Murrey, Pradhan, Sephton, Shapiro 98, Shapiro 05, Tacon	INSPIRIT, SCI, PSOM, PSI, LCB, CPAQ, CUSI, CSI, PWBS, SOC, ECRS, SCS, CECS, PF-SOC,	0.50	0.35-0.66	Tau: 0.02 I^2: 14%
Quality of Life (4 studies, 11 outcomes)	de Vibe, Grossman, Nyklicek, Shapiro 05	WHOQOLBREF, HAQUAMS, PQOLC, SWLS,	0.57	0.17-0.96	Tau^2: 0.07 I^2: 47%
Somatic outcomes (10 studies, 18 outcomes)	Davidson, de Vibe, Lengacher, Mortitz, Morone, Plews-Ogan, Pradhan, Surawy, Tacon, Wiliams	AB titre, SHC, McGPQ, SF36-Ph, PUS, DAS28, CFS, HR, TV, Vent, MSCL	0.31	0.10-0.52	Tau^2: 0.01 I^2: 11%
Mindfulness (7 studies, 11 outcomes)	Anderson, Bränström, Cohen-Katz, Klatt, Nyklicek, Pradhan, Vieten	MAAS, FFMS	0,70	0.05-1.34	Tau^2: 0.4 I^2: 82%

11.6 SUBGROUP ANALYSIS

Comparisons	Study N	Effect size difference (95% CI), p-value
Non-clinical vs. clinical populations	26	0.12 (-0.06, 0.30), p=0.17
Clinical psychological vs. clinical somatic populations	16	0.01 (-.03, 0.23), p=0.94
Studies without intention to treat (ITT) analysis vs. studies with ITT analysis	26	0.12 (-0.28, 0.03), p=0.12
Decrease in effect size for each additional month of follow-up from 0-6 months	26	-0.03 (-0.05, 0.00), p=0.03
Increase in effect size for each unit increase in risk of bias score	26	0.03 (-0.08, 0.03), p=0.32
Increase in effect size for each one hour increase in MBSR course	26	0.01 (0.00, 0.02), p=0.15
Increase in effect size for each percentage point increase in MBSR attendance between 65% and 92%	18	0.01 (0.00, 0.02), p=0.005
Increase in effect size for each minute of MBSR practice between 7 and 45 minutes/day	13	0.00 (-0.01, 0.02), p=0.48

11.7 CORRELATION MATRIX AT POST-INTERVENTION

	Clinical/ Nonclin.	Clin.Som/ Clin.Psych	ITT/ Non ITT	Risk of bias	MBSR hours	Attend. hours	Practice minutes	No of studies
Clinical/Nonclinical	1.00	Not Appl	0.61	0.35	0.05	0.50	-0.23	26
Clin.Som/Clin.Psych	Not Appl	1.00	-0.45	0.03	0.19	0.21	-0.71	16
ITT/NonITT	0.61	-0.45	1.00	0.47	-0.02	0.10	0.07	26
Risk of bias	0.35	0.03	0.47	1.00	0.13	0.17	0.05	26
MBSR hours	0.47	0.19	-0.02	0.13	1.00	0.29	-0.02	26
Attendance hours	0.50	0.21	0.10	0.17	0.29	1.00	0.06	18
Practice minutes	-0.23	-0.71	0.07	0.05	-0.02	0.06	1.00	13

Correlation matrices for the covariates in the 8 bivariate analyses. These are based on all of the effect sizes, though separated into one set at the end of the intervention and another for all values of follow-up time.

12 Appendices

12.1 STUDY INCLUSION AND EXCLUSION FORM

STUDY INCLUSION AND EXCLUSION FORM: MBSR REVIEW				
Reference ID:	**Reviewer ID**:		**Date**:	
Author:	**Year of publication:**			
1. Reported data from a primary study	**Yes**	**No**	**Uncertain**	**Notes**
2. Two or more groups randomised to intervention or control				
3. The intervention is described as MBSR				
4. The duration of the MBSR intervention is 8 weeks				
5. The study population includes adults				
6. The study aims to estimate/measure the effect of MBSR only (E.g. exclusion criterion is MBSR plus something else vs. no intervention)				
7. Study reports numeric data on at least one indicator of health, quality of life, or social function				
8. The study is included				
Additional comments:				

12.2 CODING AND DATA EXTRACTION FORM

CODING AND DATA EXTRACTION FORM: MBSR REVIEW

Reference ID: **Reviewer ID**:
Study ID: **Date**:

Year of publication:

Author:

Notes:

STUDY DESIGN

1. Intervention group(s) were formed by:
Random assignment:
Other (specify):
Not reported:
Description unclear:

2. Control group(s) were formed by:
Random assignment:
Other (specify):
Not reported:
Description unclear:

3. If random assignment specify:
Individual randomisation:
Cluster (group) randomisation:
Other (specify):
Not reported:
Description unclear:

4. How was random assignment performed?
Computer generated:
Random numbers table:
Coins/dice/shuffling:
Other (Specify):
Not reported:
Unclear description:

5. What method was used to conceal the allocation sequence?
(Was allocation adequately concealed, could assignments have been predicted?)
Sealed numbered/coded envelope:
Telephone:

No concealment:
Other (specify):
Not stated:
Unclear description:

Blinding of intervention – not applicable due to the nature of the intervention

6. Were the outcome assessors blinded?
(Assessors unaware of assignment when collecting outcome measures)
Yes:
No:
Not reported:
Unclear from description:

7. Other concerns about bias?
If 'Yes' describe here:

PATICIPANTS

8. Target population: Type of primary health problem/condition:
Clinical:
Non-clinical:
(Such as students, inmates, impoverished inner-city dwellers and corporate employees)

9. Are inclusion criteria for study participation mentioned?
No:
Yes:
If 'Yes', describe see below:
If clinical, specify main problem:
- Cardiovascular:
- Musculoskeletal:
- Psychological:
- Oncological:
- Respiratory:
- Rheumatological:
- Other (specify):

If non-clinical, specify:

Both clinical and non-clinical, specify:

10. Are exclusion criteria for study participation mentioned?
No:
Yes:
If 'Yes', describe (cite page number):

STUDY SAMPLE

11. Number of cases	MSBR n =	Control n =	Total	Notes & pp.

in sample	(Add columns as required)	(Add columns as required)	n =	no.
a. Eligible sample size				
b. Number randomised				
c. In final sample at start of treatment				
d. Completed treatment				
e. End point measurement				
f. % attrition and reasons				

BASELINE CHARACTERISTICS OF PARTICPIANTS

12. Were there any differences between programme and control groups at baseline?
Yes (describe differences):
No:
Not reported:

13. Was there any analysis of differences between completers and dropouts in the MBSR group?
Yes (describe differences):
No:
Not reported:

14. Was there any analysis of differences between completers and dropouts in the control group?
Yes (describe differences):
No:
Not reported:

15. Was intention to treat analysis used by investigators?
Yes:
No:
Not reported :
If 'Yes', describe:
(E.g. last measure used, or analysis explores best and worst measure scenarios etc.)

20. OUTCOME CHARACTERISTICS

Instrument/ unit	**Outcome definition** What does the scale measure, e.g. stress, depression, or a combination of these? Direction of scale. Is the scale described as validated? Cite	**Timing of measurement** State exact times within the categories below			
		<3 months	3-6 months	>6-12 months	>12 months

	how the study has described this outcome
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

21. RESULTS: Data will be extracted as reported and entered in Excel and exported into Revman5

Outcome	Intervention group 1		Control 1		Between- group analysis
	Baseline	Final	Baseline	Final	Values for p, df, t, f, and Other
	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

22. Outcome bias

Are there outcomes that were measured but not reported?
If 'Yes', are the reasons for this reported?

23. Miscellaneous

Specific source of funding
- Pharmaceutical industry:
- Internal funds:
- Professional org.:
- Other industry:
- Government:
- Other (specify):

Key conclusions of study authors:

Special comments by study authors:

Comments by reviewers:

Reference to other studies:

Contact details of the authors:

Need to contact authors:
If 'Yes', list issue(s), content and date contacted:

Additional comments:

12.3 SEARCH TERMS

Ovid MEDLINE(R) 1950 to July Week 1 2008
10.07.08

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4
6 randomized controlled trial.pt.
7 controlled clinical trial.pt.
8 randomized.ab.
9 placebo.ab.
10 drug therapy.fs.
11 randomly.ab.
12 trial.ab.
13 groups.ab.
14 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 humans.sh.
16 14 and 15
17 5 and 16

AMED (Allied and Complementary Medicine) 1985 to July 2008
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 o/1-4

PsycINFO 1806 to July Week 2 2008
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 Mindfulness/
4 mindfulnes$.ti,ab.
5 mbsr$.ti,ab.
6 or/1-5
7 empirical methods/
8 Experimental methods/
9 Quasi experimental methods/
10 experimental design/
11 between groups design/

12 followup studies/
13 repeated measures/
14 experiment controls/
15 experimental replication/
16 exp "sampling (experimental)"/
17 placebo/
18 clinical trials/
19 treatment effectiveness evaluation/
20 experimental replication.md.
21 followup study.md.
22 prospective study.md.
23 treatment outcome clinical trial.md.
24 placebo$.tw.
25 randomi?ed controlled trial$.tw.
26 rct.tw.
27 random allocation.tw.
28 (randomly adj1 allocated).tw.
29 (allocated adj2 random).tw.
30 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
31 (clinic$ adj (trial? or stud$3)).tw.
32 or/7-31
33 comment reply.dt.
34 editorial.dt.
35 letter.dt.
36 clinical case study.md.
37 nonclinical case study.md.
38 animal.po.
39 human.po.
40 38 not (38 and 39)
41 or/33-37,40
42 32 not 41
43 6 and 42

EMBASE 1980 to 2008 Week 27
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4
6 Clinical Trial/
7 Randomized Controlled Trial/
8 Randomization/
9 Double Blind Procedure/

10 Single Blind Procedure/
11 Crossover Procedure/
12 PLACEBO/
13 placebo$.tw.
14 randomi?ed controlled trial$.tw.
15 rct.tw.
16 random allocation.tw.
17 randomly allocated.tw.
18 allocated randomly.tw.
19 (allocated adj2 random).tw.
20 single blind$.tw.
21 double blind$.tw.
22 ((treble or triple) adj blind$).tw.
23 Prospective study/
24 or/6-23
25 Case study/
26 case report.tw.
27 Abstract report/
28 Letter/
29 Human/
30 Nonhuman/
31ANIMAL/
32 Animal Experiment/
33 30 or 31 or 32
34 33 not (29 and 33)
35 or/25-28,34
36 24 not 35
37 5 and 36

Ovid Nursing Full Text Plus 1950 to July Week 1 2008
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4

British Nursing Index and Archive 1985 to July 2008
10.07.2008

1 meditat$.ti,ab.
2 mindfulnes$.ti,ab.
3 mbsr$.ti,ab.
4 or/1-3

Wiley, Cochrane Library Issue 2, 2008

10.07.2008

#1 MeSH descriptor Meditation explode all trees

#2 (meditat* or mindfulnes* or mbsr$):ti,ab

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Search term: mbsr

Search term: mindfulness-based

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Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

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Topic=(randomized) OR Topic=(placebo) OR Topic=(randomly) OR Topic=(trial) OR Topic=(groups) OR Topic=(controlled)

Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

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Topic=(meditat*) OR Topic=(mindfulnes*) OR Topic=(mbsr*)

Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

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S1 Explodesökning på Meditation

S2 mindfulnes$

S3 mbsr$

S4 oppmerksomhetstrening$

S5 uppmärksamhetsträning$

S6 s1 or s2 or s3 or s4 or s5

Google

11.07.2008

Hits only entered if unique to this search (i.e. not retrieved in other databases)

We went through the first 100 hits.

research OR evaluation OR evaluations OR outcome OR outcomes OR effect OR effects OR trial OR trials OR study OR studies "mindfulness based stress reduction"

CSA ERIC

06.11.2008

TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)
Limited to: Publication Type is PT=(142 reports: evaluative) or PT=(143 reports: research)

CSA Sociological Abstracts

06.11.2008
(TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)) and((TI=(random* or control* or trial*) or TI=(group* or placebo* or experiment* or evaluat*) or TI=(prospectiv* or (compar* within 2 (trial* or study or studies)))) or(AB=(random* or control* or trial*) or AB=(group* or placebo* or experiment* or evaluat*) or AB=(prospectiv* or (compar* within 2 (trial* or study or studies)))))

CSA Social Services Abstracts

06.11.2008
TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)

OVID International Bibliography of the Social Sciences

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2 meditat$.tw.
3 mindfulnes$.tw.
4 mbsr$.tw.
5 or/1-4
6 random$.tw.
7 control$.tw.
8 trial$.tw.
9 group$.tw.
10 placebo$.tw.
11 experiment$.tw.
12evaluat$.tw.
13((prospectiv$ or compar*) adj2 (trial* or study or studies)).tw.
14or/6-13
1514 and 5

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(mindfulnes* or mbsr) and (random* or control* or trial* or group* or placebo* or experiment* or evaluat*)

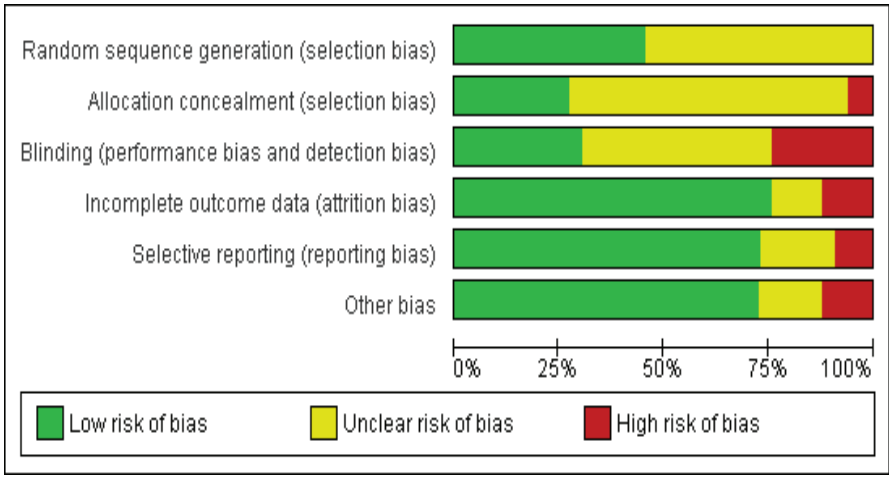
Dissertation Abstracts

15.10.2008

Mindfulness-based

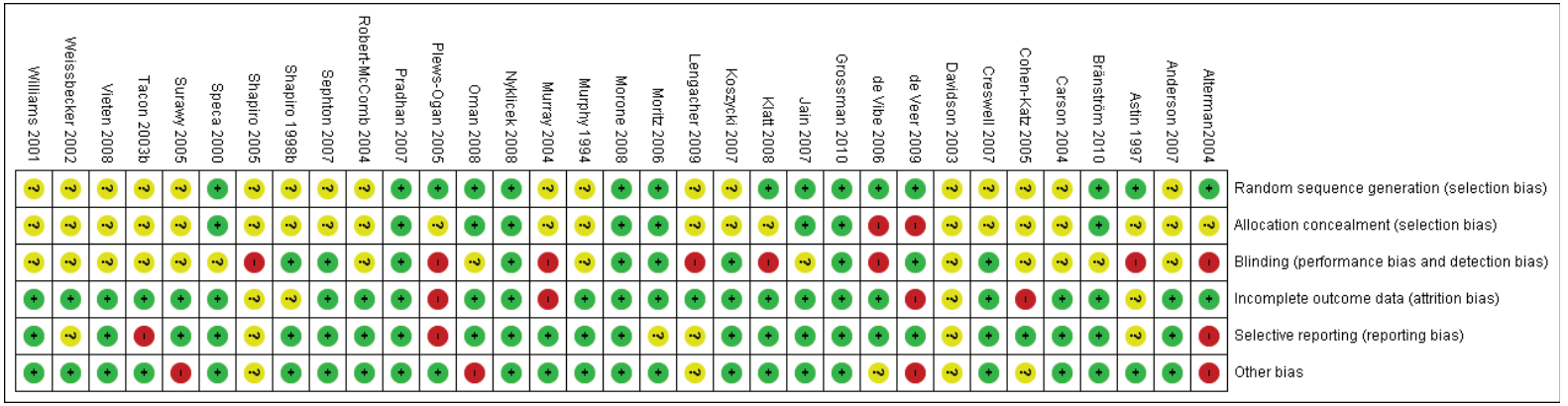
13 Figures

13.1 METHODOLOGICAL QUALITY GRAPH



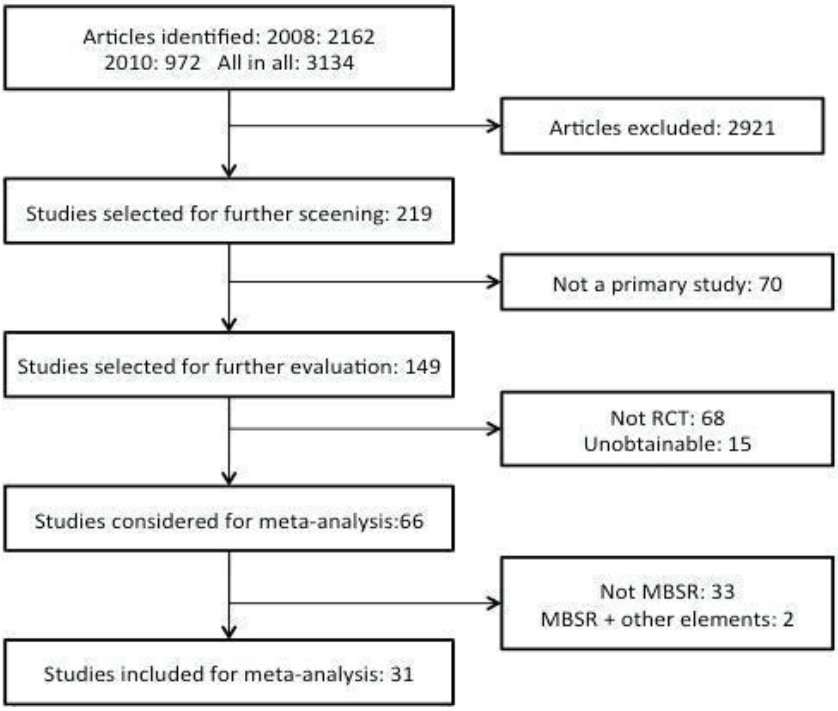
Review authors' judgements about each methodological quality item (shown as percentages across all included studies)

13.2 METHODOLOGICAL QUALITY SUMMARY



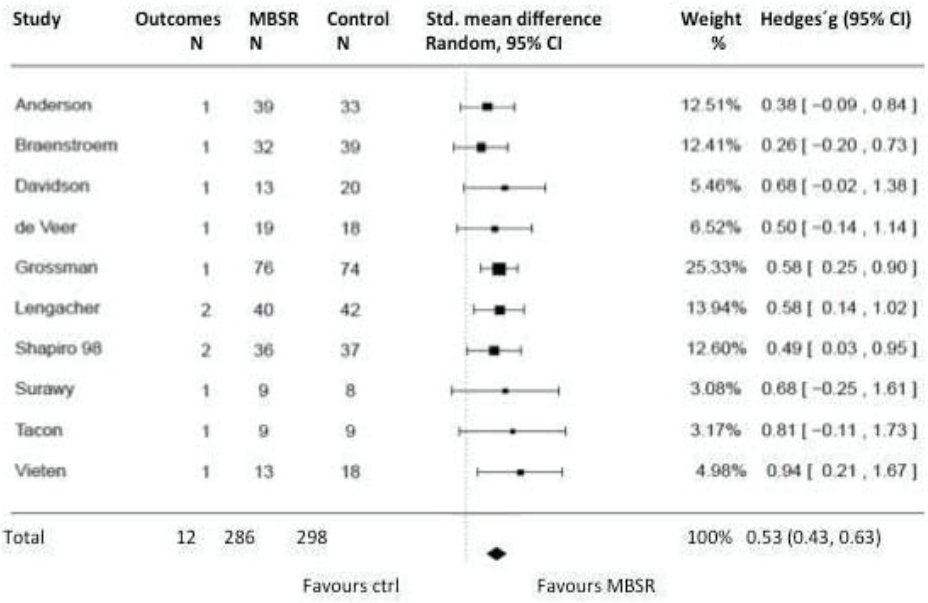
Review authors' judgements about each methodological quality item for each included study

13.3 SEARCH RESULTS AND INCLUSION OF STUDIES



13.4 EFFECTS ON ANXIETY SCORES (USING ROBUST SE)

Figure 4
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Anxiety Score

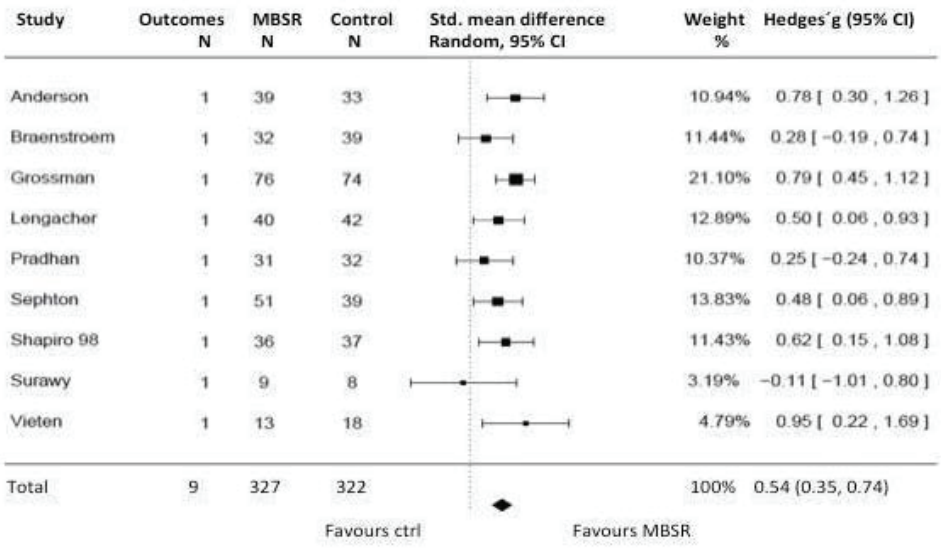


Heterogeneity: $Tau^2 = 0.0$, $I^2 = 0\%$

13.5 EFFECTS ON DEPRESSION SCORES (USING NORMAL SE)

Figure 5
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU

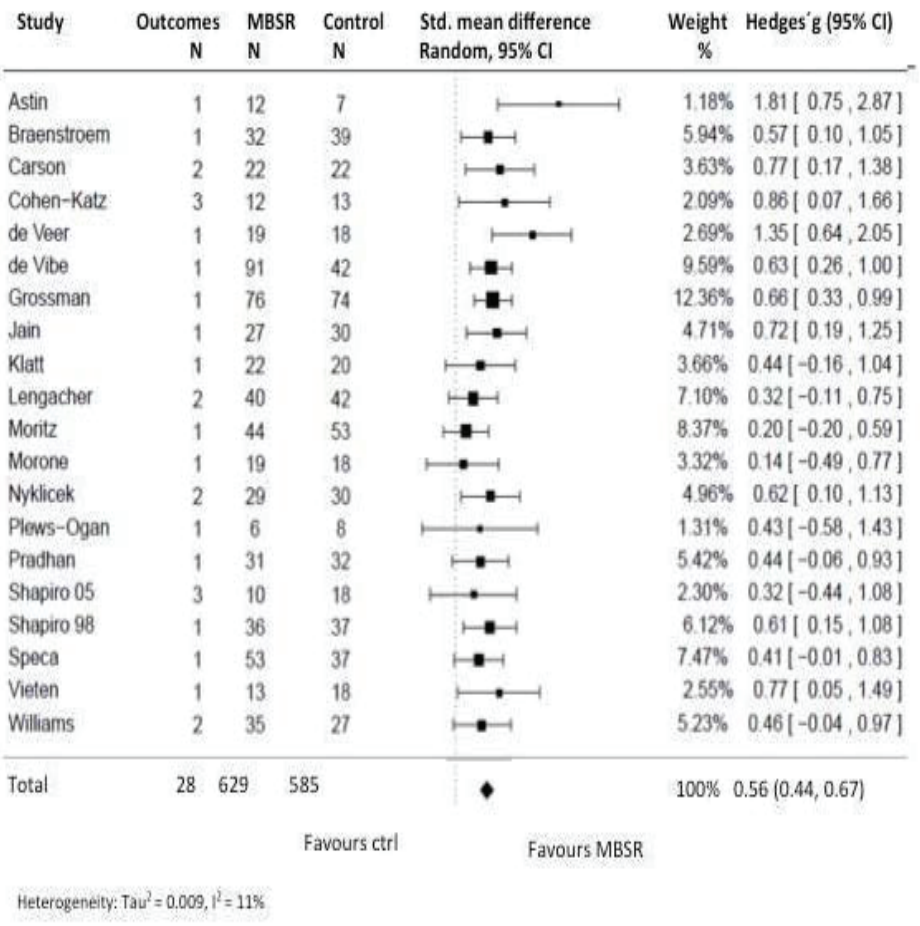
Outcome: Composite Depression Score



Heterogeneity: $Tau^2 = 0.03$, $I^2 = 32\%$

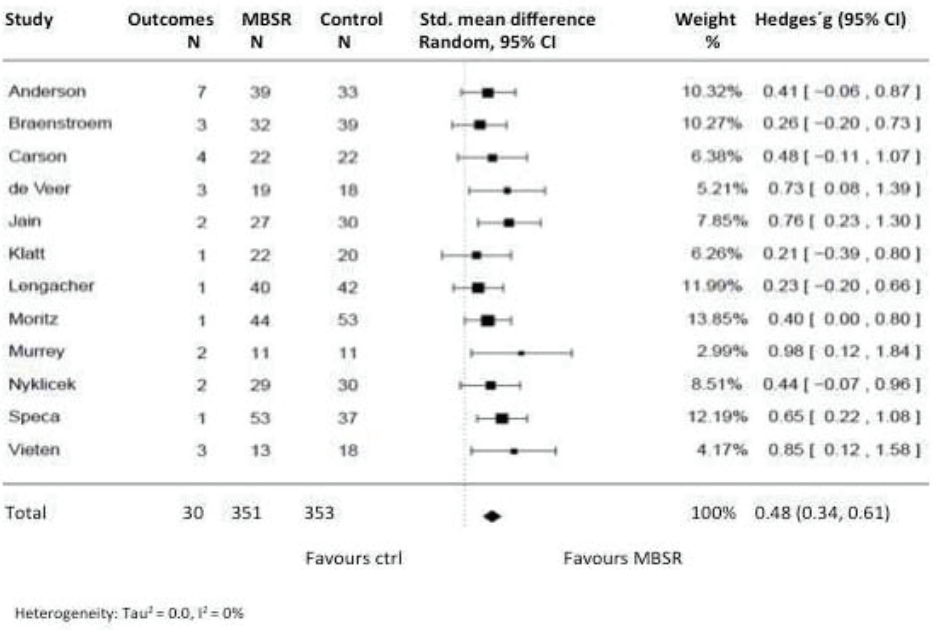
13.6 EFFECTS ON STRESS SCORES (USING ROBUST SE)

Figure 6
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Stress Score



13.7 EFFECTS ON OTHER MENTAL HEALTH SCORES (USING ROBUST SE)

Figure 7
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Other Mental Health Score



Heterogeneity: $Tau^2 = 0.0$, $I^2 = 0\%$

13.8 EFFECTS ON COMPOSITE MENTAL HEALTH SCORE (USING ROBUST SE)

Figure 8
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Mental Health Score

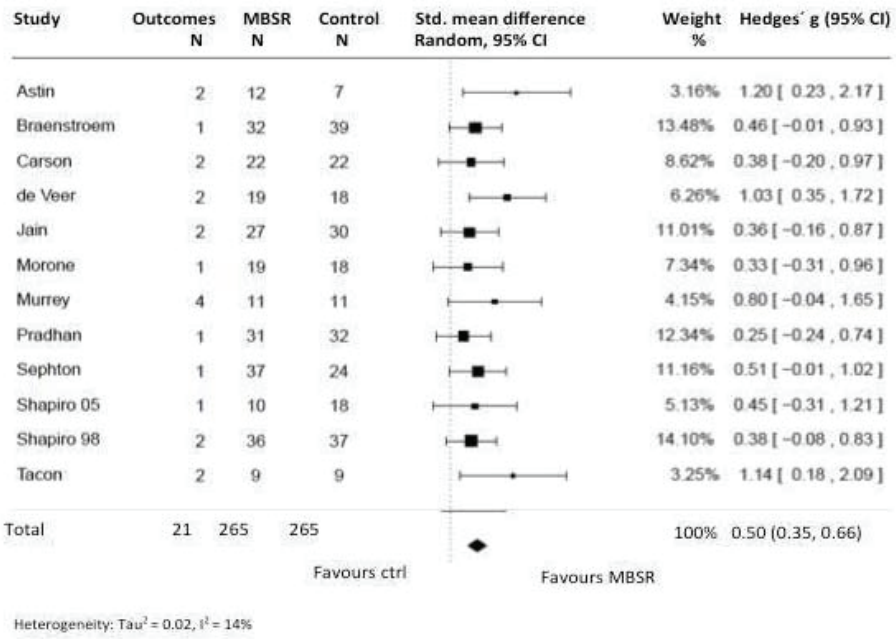
Study	Outcomes N	MBSR N	Control N	Std. mean difference Random, 95% CI	Weight %	Hedges´g (95% CI)
Anderson	9	39	33		5.02%	0.44 [−0.02 , 0.91]
Astin	1	12	7		0.97%	1.81 [0.75 , 2.87]
Braenstroem	6	32	39		5.01%	0.32 [−0.15 , 0.78]
Carson	6	22	22		3.07%	0.58 [−0.02 , 1.17]
Cohen−Katz	3	12	13		1.72%	0.86 [0.07 , 1.66]
Davidson	1	13	20		2.22%	0.68 [−0.02 , 1.38]
de Veer	5	19	18		2.49%	0.81 [0.15 , 1.47]
de Vibe	1	91	42		7.89%	0.63 [0.26 , 1.00]
Grossman	3	76	74		10.13%	0.67 [0.35 , 1.00]
Jain	3	27	30		3.85%	0.75 [0.22 , 1.28]
Klatt	2	22	20		3.03%	0.32 [−0.27 , 0.92]
Lengacher	6	40	42		5.76%	0.42 [−0.01 , 0.85]
Moritz	2	44	53		6.83%	0.30 [−0.10 , 0.70]
Morone	1	19	18		2.73%	0.14 [−0.49 , 0.77]
Murrey	2	11	11		1.47%	0.98 [0.12 , 1.84]
Nyklicek	4	29	30		4.12%	0.53 [0.02 , 1.04]
Plews−Ogan	1	6	8		1.08%	0.43 [−0.58 , 1.43]
Pradhan	2	31	32		4.49%	0.35 [−0.15 , 0.84]
Sephton	1	51	39		6.19%	0.48 [0.06 , 0.89]
Shapiro 05	3	10	18		1.89%	0.32 [−0.44 , 1.08]
Shapiro 98	4	36	37		5.07%	0.55 [0.09 , 1.02]
Speca	2	53	37		6.05%	0.53 [0.11 , 0.96]
Surawy	2	9	8		1.29%	0.29 [−0.63 , 1.20]
Tacon	1	9	9		1.29%	0.81 [−0.11 , 1.73]
Vieten	6	13	18		2.04%	0.87 [0.14 , 1.60]
Williams	2	35	27		4.30%	0.46 [−0.04 , 0.97]
Total	76	751	705		100%	0.53 (0.46, 0.61)

Favours ctrl Favours MBSR

Heterogeneity: $tau^2 = 0.0$, $I^2 = 0\%$

13.9 EFFECTS ON PERSONAL DEVELOPMENT SCORES (USING ROBUST SE)

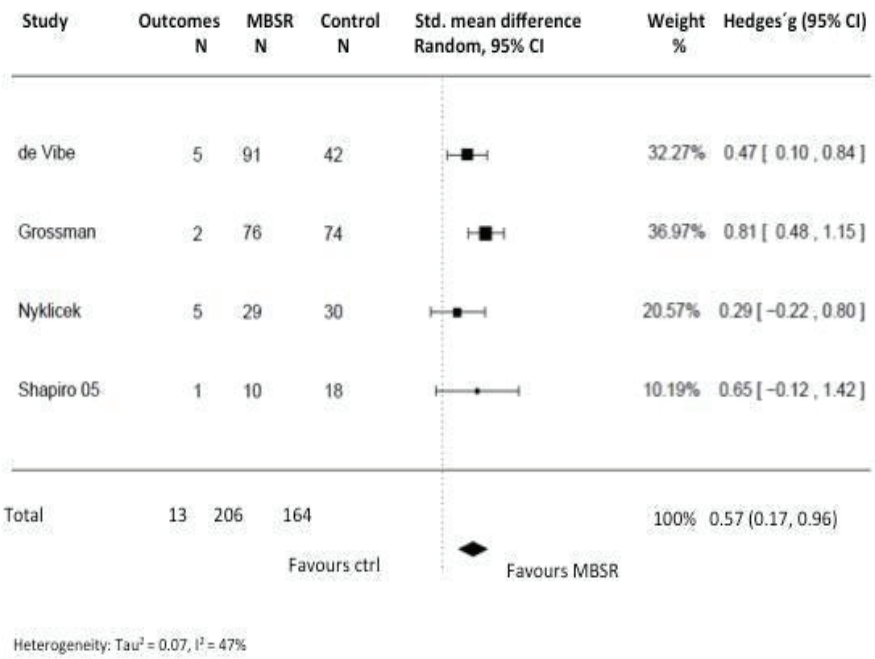
Figure 9
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Personal Development Score



Heterogeneity: $Tau^2 = 0.02$, $I^2 = 14\%$

13.10 EFFECTS ON QUALITY OF LIFE SCORES (USING ROBUST SE)

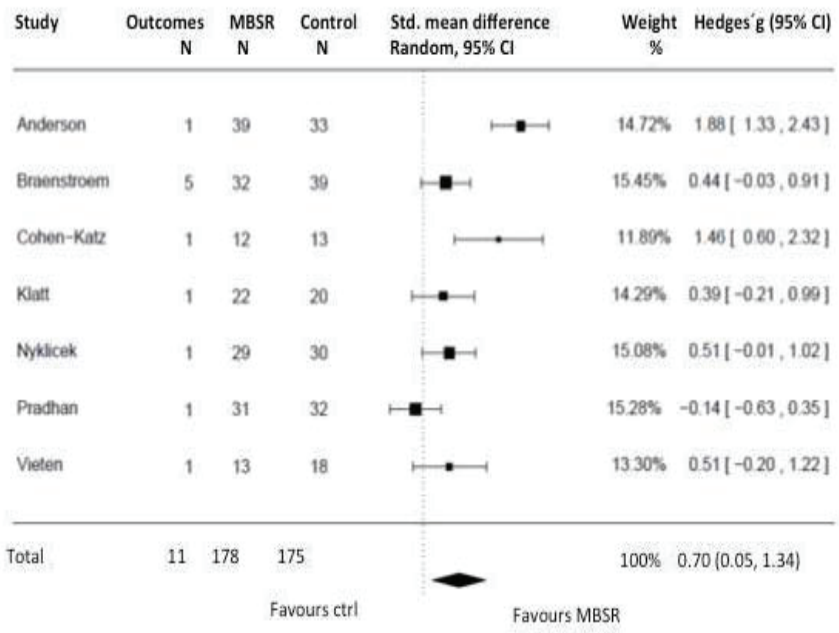
Figure 10
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Quality of Life Score



Heterogeneity: $Tau^2 = 0.07$, $I^2 = 47\%$

13.11 EFFECTS ON MINDFULNESS MEASURES (USING ROBUST SE)

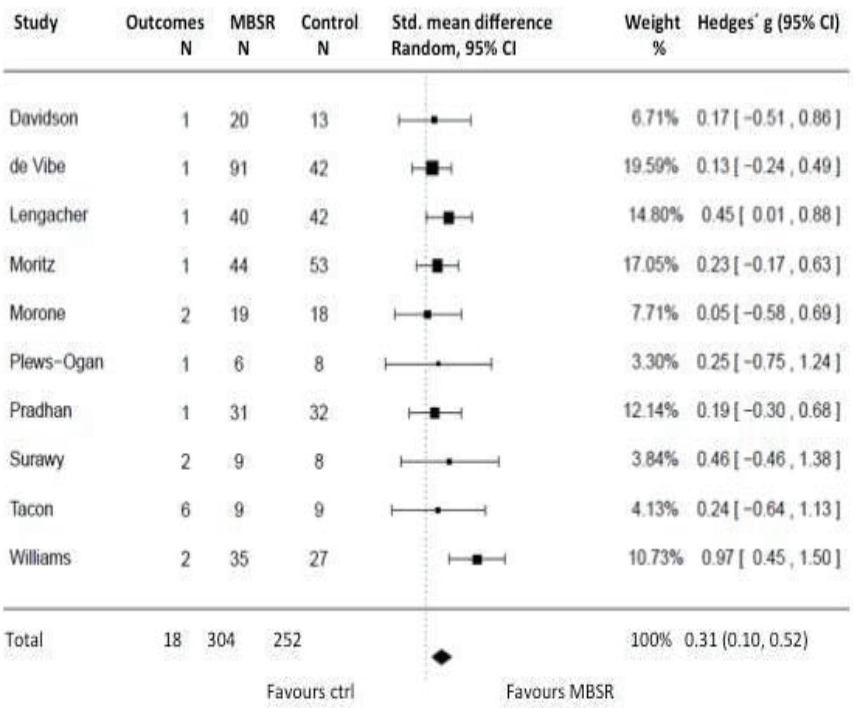
Figure 11
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Mindfulness Score



Heterogeneity: $Tau^2 = 0.40$, $I^2 = 82\%$

13.12 EFFECTS ON SOMATIC HEALTH SCORES (USING ROBUST SE)

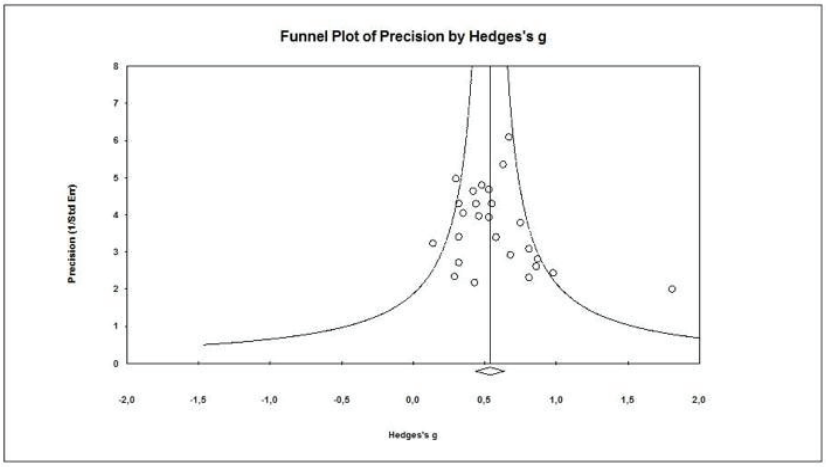
Figure 12
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Somatic Health Score



Heterogeneity: $Tau^2 = 0.01$, $I^2 = 11\%$

13.13 FUNNEL PLOT OF PRECISION VERSUS EFFECT SIZES

Composite Mental Health Outcome Hedges`g from 26 RCT studies on MBSR



Fail safe N (Rosenthal): Number of missing studies that would bring the p value to > 0.05 = 689
Fail safe N (Orwin) : Number of missing studies with zero effect, that would reduce Hedges` g to < 0.2 = 44
Egger´s test: Intercept 0.95 (CI -0,24, 2,15)

13.14 GRADE SCORES

Mindfulness Based Stress Reduction (MBSR) for improving health, quality of life and social function in adults

Patient or population: both patients and healthy people
Settings: All settings, **Intervention:** MBSR; **Comparison:** Wait-list or TAU

Outcomes	Hedges´ g	Hedges´ g (95% CI)	No of Participants	Quality of the evidence (GRADE)
Mental Health Outcome Pooled estimate of 79 mental health outcomes in 26 studies using robust SE	0.53	(0.46, 0.61)	1456	⊕⊕⊕⊕ **high**[1,2,3,4,5,6]
Stress Outcome Pooled estimate of 28 stress outcomes in 20 studies using robust SE	0.56	(0.44, 0.67)	1214	⊕⊕⊕⊕ **high**[1,2,3,5]
Anxiety Outcome Pooled estimate of 12 anxiety outcomes in 10 studies using robust SE	0.53	(0.43, 0.63)	584	⊕⊕⊕⊖ **moderate**[2,3,5,8]
Depression Outcome Pooled estimate of 9 depression outcomes in 9 studies using standard SE	0.54	(0.35, 0.74)	649	⊕⊕⊕⊖ **moderate**[2,8,]
Somatic Health Outcome Pooled estimate of 18 somatic health outcomes in 10 studies using robust SE	0.31	(0.10, 0,52)	556	⊕⊕⊕⊖ **moderate**[7]
Personal development Outcome Pooled estimate of 21 personal development outcomes in 12 studies using robust SE	0.50	(0.35, 0.66)	530	⊕⊕⊕⊖ **moderate** [8]
Quality of Life Outcome Pooled estimate of 13 personal development outcomes in 4 studies using robust SE	0.57	(0.17, 0.96)	370	⊕⊕⊖⊖ **low**[8,9]

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] 14 studies did not specify sequence generation. 22 studies did not specify whether concealment of allocation was adequate. 15 studies did not report on blinding. Not rated down as there was no significant influence of increasing risk of bias score on the effect size, p=.29
[2] Results consistent across studies using different populations and different lengths of MBSR intervention, [3] $\tau^2 = 0.0$ and $I^2 = 0\%$ for mental health and anxiety and 0.009 and 11% for stress, showing low heterogeneity. [4] All studies in meta-analysis entered data, [5] Some small studies, but effect sizes adjusted for sample size, robust SE used in meta-analysis and CI acceptable
[6] 23 studies without reporting bias, [7] Very different somatic outcomes used, and wider CIs, more studies with similar outcomes necessary to assess certain effect [8] Relatively few studies, [9] $\tau^2 = 0.065$ and I^2=47% showing risk of heterogeneity

II

de Vibe et al. BMC Medical Education 2013, 13:107
http://www.biomedcentral.com/1472-6920/13/107

BMC Medical Education

RESEARCH ARTICLE Open Access

Mindfulness training for stress management: a randomised controlled study of medical and psychology students

Michael de Vibe[1†], Ida Solhaug[2*†], Reidar Tyssen[3], Oddgeir Friborg[2,4], Jan H Rosenvinge[2,4], Tore Sørlie[5,6] and Arild Bjørndal[7]

Abstract

Background: Distress and burnout among medical and psychology professionals are commonly reported and have implications for the quality of patient care delivered. Already in the course of university studies, medicine and psychology students report mental distress and low life satisfaction. There is a need for interventions that promote better coping skills in students in order to prevent distress and future burnout. This study examines the effect of a seven-week Mindfulness-Based Stress Reduction (MBSR) programme on mental distress, study stress, burnout, subjective well-being, and mindfulness of medical and psychology students.

Methods: A total of 288 students (mean age = 23 years, 76% female) from the University of Oslo and the University of Tromsø were randomly allocated to an intervention or control group. The control group continued with their standard university courses and received no intervention. Participants were evaluated using self-reported measures both before and after the intervention. These were: the 'General Health Questionnaire, Maslach Burnout Inventory Student version, Perceived Medical School Stress, Subjective Well-being, and Five Facet Mindfulness Questionnaire' and additional indices of compliance.

Results: Following the intervention, a moderate effect on mental distress (Hedges'g 0.65, CI = .41, .88), and a small effect on both subjective well-being (Hedges'g 0.40, CI = .27, .63) and the mindfulness facet 'non-reacting' (Hedges'g 0.33, CI = .10, .56) were found in the intervention group compared with the control group. A higher level of programme attendance and reported mindfulness exercises predicted these changes. Significant effects were only found for female students who additionally reported reduced study stress and an increase in the mindfulness facet 'non-judging'. Gender specific effects of participation in the MBSR programme have not previously been reported, and gender differences in the present study are discussed.

Conclusion: Female medical and psychology students experienced significant positive improvements in mental distress, study stress, subjective well-being and mindfulness after participating in the MBSR programme.

Trial registration: NCT00892138

Keywords: Stress management, Mental distress, Well-being, Five facet mindfulness questionnaire, Gender differences, Undergraduate medical and psychology education

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Full list of author information is available at the end of the article

Background

Distress among medical and psychology professionals is associated with poorer patient care [1], a higher risk of future medical errors [2], as well as depression, anxiety and reduced life satisfaction [3-5]. Whether such problems can be prevented through stress-reducing interventions for psychology and medical students has not yet been fully investigated, and there are noticeably few studies involving psychology students within this area of research. In Norway, admission criteria to both the medicine and psychology professional study are very high. Medical and psychology students are typically resourceful high achievers who are able to cope with the challenges of professional study yet they also commonly report mental distress and low levels of life satisfaction [6-8]. A review of the distress experienced by medical students has emphasised the need for studies that contribute to a better understanding of how to promote well-being [9]. A failure to promote well-being may lower academic performance [10,11]. Other studies have addressed the need to prevent future potential stress and burnout through the teaching of better coping skills to students [8,12,13]. There is currently a shortage of well-designed and effective intervention studies to address such challenges.

Mindfulness-Based Stress Reduction (MBSR) has been used increasingly over the last 30 years to help people cope with physical and mental distress. By cultivating an open, accepting attitude within the present moment towards internal and external experiences, MBSR training has been shown to reduce mental distress and promote well-being in both clinical and non-clinical populations [14]. Previous studies of mindfulness training given to medical students in the United States of America (USA) and Australia have reported beneficial outcomes [15-18]. Few studies of mindfulness training have been undertaken on psychology students [19,20]. Although these studies have indicated similar beneficial results they have suffered from both poor statistical strength and inadequate randomisation and this has limited the validity of their conclusions. To date, there has also been a lack of studies comparing the effects of mindfulness-based interventions on medical and psychology students as well as multi-site studies which could facilitate the generalisation of results.

Many studies have indicated that women report higher levels of distress and lower levels of subjective well-being than men [21-23] but the field is still characterised by a lack of attention to gender-specific effects. A meta-analysis of 31 randomised controlled MBSR trials identified only two studies that had analysed gender as a moderator variable and neither of these reported gender-specific effects [14].

There is a growing body of research indicating that MBSR programmes lead to increased levels of participant self-reported mindfulness [14] but such findings have not yet been confirmed in a randomised controlled study of students. In studies of the effects of MBSR programmes, moderator variables such as course attendance and mindfulness practice have also been examined in several studies but the results have been mixed [14]. This may be due to variations in the power of such studies to detect effects [24].

Our study aimed to evaluate the effects of a seven-week MBSR programme in a student sample from two Norwegian universities. The study had three main aims: first, to test the hypothesis that the MBSR programme would enhance mental health among medical and psychology students as measured by multiple dimensions of psychological health and well-being. Second, we aimed to test whether the intervention effects were influenced by gender, the university courses (psychology or medicine), the university locations, course instructors, intervention participation and self-reported mindfulness practice. Finally, we aimed to assess our expectation that the MBSR intervention would increase facets of mindfulness.

Methods

Participants and recruitment

In 2009 and 2010, medical and psychology students in their second or third term at the University of Oslo and the University of Tromsø respectively, were invited to participate in the study. Information was provided during classes by the study project managers followed by an email inviting people to visit a website for more information and the opportunity to sign up for the study. Informed consent was obtained electronically after which the participants completed an online questionnaire (T1). Because the programme purpose was health promotion and stress management rather than psychotherapy, no exclusion criteria were used and the students were not screened for mental illness. The sample size was calculated based on an expected reduction in mental distress and perceived medical school stress of 20% in the intervention group, and on longitudinal studies of how stress and mental health problems increase during university programmes among Norwegian medical students [25,26]. 60–100 participants per study group were needed for the power calculation (alpha level .05, 80% power) to test whether the intervention could prevent such increases. The study protocol is available at www.clinicaltrials.gov [27], where further details on sample calculation can be found.

Procedures

After the participants completed the T1 questionnaire, a computer program (a Java-based random number generator) was used to randomly assign students either to the intervention group or to the control group. The randomisation was performed separately for each class of students without stratification by gender. An email message sent two weeks prior to the intervention informed

the study participants of their group allocation. Within the two weeks after the intervention, participants were asked to complete a second questionnaire (T2) and they received up to three email reminders to prompt them to do so. The head technician at the Norwegian Knowledge Centre for the Health Services assigned each participant an identity (ID) number which was then assigned to their online questionnaires to ensure that the data remained anonymous. Only the head technician had access to data that showed the link between the student identities and the ID numbers, and he was not involved in the study in any other way.

To compensate study participants for using approximately 40 minutes to complete the T1 and T2 questionnaires each time and to reduce potential drop-out rates, those students who took part in the study received a book voucher after they had completed the T2 questionnaire. The study was approved by the Regional Committee for Medical and Health Research Ethics in Norway, and by the Norwegian Data Inspectorate.

Description of the intervention

The MBSR programme – based on the programme developed by Kabat-Zinn [28] – was conducted independently of the students' study curricula and lasted seven weeks. The original programme consisted of eight weekly sessions of 2.5 hours each, a 7-hour session that took place between week six and seven and 45 minutes of formal mindfulness practice at home. However, information obtained from the focus group interviews with students prior to the study led to the programme being reduced to six weekly sessions of 1.5 hours each, a 6-hour session in week seven, and 30 minutes of daily home mindfulness practice. Apart from these changes, the intervention was equivalent to the original MBSR programme.

The MBSR programme used in this study consisted of: 1) physical and mental exercises to increase participant mindfulness of experiences in the present moment, 2) didactic teaching on mindfulness, stress, stress management and mindful communication, using a course manual and CDs for home practice, and 3) a group process to facilitate reflections on practising mindfulness both at home and during classes. The instructors focused on creating an open, curious, non-judgemental and accepting attitude towards all participant experiences. The course manual used in this study is available on request.

Instructor qualifications and compliance with the MBSR manual

The instructors (three men and three women) were trained in conducting MBSR courses and had practiced mindfulness for many years. Both project managers received their instructor training provided by the Center for Mindfulness in Massachussets, USA, and were in agreement regarding the content and format of the MBSR course manual. When running the first course they also consulted each other after every class to ensure programme fidelity.

Measures

In addition to the information gathered about participant age, gender, marital status (coded as 'single' or 'living with partner') and how many children they had (coded as 'none' or 'having children'), outcome measures were chosen that would capture the possible intervention effects on different aspects of psychological health, including mental distress, study stress, student burnout, subjective well-being, and mindfulness. We also measured student compliance as indicated by course attendance and self-reported home practice.

Mental distress was measured using the 12-item General Health Questionnaire (GHQ12) [29]. This consisted of questions related to participant mental distress experience in the last two weeks and used four evaluation response categories: 'more than usual' (0), 'same as usual' (1), 'less than usual' (2), and 'much less than usual' (3). The total possible score ranged from 0 (no distress) to 36. The Cronbach's alpha value for our sample was .90. The GHQ12 response categories were further dichotomised, with '0'-'1' evaluations scored as '0' while '2'-'3' evaluations were scored as '1'. A cut-off score of '≥4' indicated a clinically significant level of mental distress [23].

Student burnout was measured using a version of the 15-item Maslach Burnout Inventory (MBI) tailored to measure three dimensions of student burnout, namely: emotional exhaustion (5 items), cynicism (4 items), and study efficacy (6 items) [30]. The items had seven response categories ranging from 'never' (0) to 'always' (6). A summed score was calculated based on a reversal of the efficacy items and evaluated on a scale ranging from 0 (indicating 'no burnout') to 90. The MBI inventory is cross-culturally valid, has good psychometric properties [30], and has been tested on pre-clinical and clinical medical students [31]. In our sample, the Cronbach's alpha value for the sum scale was .90.

Study stress was measured using the 13-item Perceived Medical School Stress (PMSS) scale [32], with one item adapted for cultural reasons [33]. The PMSS assessment has been shown to have adequate predictive validity for mental health problems in medical professionals four years after graduation [34]. In our study, the PMSS was adapted by removing the word 'medical' in all instances of the term 'medical study'. The 13 items had five response categories which ranged from 'strongly disagree' (0) to 'strongly agree' (4), and the total sum score ranged from 0 (indicating 'no stress') to 52. The Cronbach's alpha value for our sample was .79.

Subjective well-being (SWB) was measured using a 4-item version of the SWB scale [35]. Previous use of this scale has indicated that is has good psychometric properties and correlates strongly and positively with the Satisfaction With Life Scale [36]. In accordance with generally accepted dimensions of well-being scales [36], the SWB construct consists of a cognitive element (life satisfaction), a positive affect element (happy and strong) and a negative affect element (unhappy and tired). The number of the response categories varied and therefore all items were transformed to a scale ranging from 0–10, using the algorithm: $X = (Y-1) \times 10/(Z-1)$, where X is the new score, Y the original score, and Z the number of response categories. Higher scores reflect increased subjective well-being. The Cronbach's alpha value for our sample was .81.

Mindfulness was measured using the Five Facet Mindfulness Questionnaire (FFMQ; 39 items). This questionnaire has been shown to have good psychometric properties [37] and was used in our study to measure five facets of mindfulness. The Norwegian version of the questionnaire was translated using a standard forward-backward process at the University of Bergen and has also been used in a recent Norwegian MBSR study [38]. The first four facets consisted of eight items each, while the fifth had seven items. Each item had five response categories which ranged from 'never or very seldom true' (1) to 'very often or always true' (5). In our sample, the five facets (and corresponding Cronbach's alpha values) were: the ability to a) observe (.78), b) describe (.89), c) act with awareness (.88) together with the ability to be fully present with an attitude of d) non-judgement (.92), and e) non-reactivity (.73) towards what occurs. Suboptimal properties of the non-reactivity facet in a student sample have also been found in previous research [37]. In student populations the FFMQ is positively correlated with meditation experience, openness to experience, emotional intelligence and self-compassion. It is also strongly negatively correlated with psychological symptoms, neuroticism, thought suppression and difficulties in emotional regulation [37]. Higher scores indicate increased mindfulness.

Student compliance measured attendance and self-reported home-based mindfulness practice. *Attendance* was measured by the number of classes attended (0-7). *Mindfulness practice* was assessed using four questions: a) 'How often have you practised mindfulness exercises (body-scan, relaxation, yoga, gi gong, tai chi or meditation) in the last four weeks?' (the six response categories ranged from 'never' (0) to 'daily' (5)); b) 'When you practise, how long do you normally practise?' (six response categories which ranged from 0 minutes (0) to >45 minutes (5)); c) 'How often have you practised mindful breathing in the last four weeks?' (six response categories which ranged from 'never' (0) to 'daily' (5)), and d) 'How often have you practised being mindful in everyday situations in the last four weeks?' (six response categories which ranged from 'never' (0) to 'daily' (5)). Mindfulness practice was measured as a summed score (ranging from 0 to 20).

Statistical analyses

The success of the randomisation procedure was evaluated by analysing T1 mean score differences between the intervention and control groups using independent sample t-tests and chi-square test for categorical variables. Completer and dropout comparisons were also examined using the same tests. The online questionnaire was constructed in a way that ensured that all items on each page had to be completed before respondents were able to progress to the next page. Instances of missing data were caused by discontinuation of the questionnaire (one student) or a loss of respondents to follow-up (eleven students). Data were missing from the responses of five students in the intervention group and seven in the control group respectively. The last-observation-carried-forward method of imputation was chosen as this is a conservative method used in instances in which there is an equal drop-out rate in the intervention and the control group [39]. Intention-to-treat analyses and per protocol analyses yielded very similar results and we have therefore presented only the former.

Multivariate analyses of covariance (MANCOVA) were applied to the multiple dependent variables measured at T2 (i.e. mental distress, student burnout, study stress, and subjective well-being). Analyses of covariance (ANCOVAs) were then applied. T1 measures were included as covariates because the correlation coefficients between the measurements at T1 and T2 were substantial. The use of covariate control increased the statistical strength of the results by reducing unexplained or error variance. This same approach was used to examine the effect of the intervention on the five facets measuring mindfulness. As gender had not been accounted for by stratified randomisation, this was included as a factor in the MANCOVA analysis in order to estimate its effect on the intervention. Alpha-levels were adjusted for multiple testing by applying a Bonferroni correction.

A linear regression analysis was used to test the relationship between MBSR attendance and mindfulness practice and the outcome variables. Multilevel mixed linear regression analyses were conducted to investigate whether MBSR effects depended on the student class (five medicine and five psychology classes as random factors) or the university locations (Oslo and Tromsø as fixed factors). The study instructors varied by university location and these factors therefore coincided. Mediation analyses will be conducted following collection of two-year follow-up data.

Hedges' g was used to calculate the size of the treatment effect by estimating the standardised mean difference in test scores between the intervention and control group (Tables 1 and 2). Hedges' g is similar to Cohen's d (with a pooled SD) but has slightly improved precision as the result of the inclusion of a correction factor for small sample sizes. The two effect-sizes are related accorded to the equation $g = \sqrt{\frac{n_1+n_2-2}{n_1+n_2}}d$, and the values used for interpreting effect size are 0.2 (small), 0.5 (moderate) and 0.8 (large) [40]. We calculated the Number Needed to Treat (NNT) which was used as a measure to assess the clinical importance of the effect found on mental distress. NNT is defined as the expected number of people that need to receive an intervention rather than the control condition for one additional person to have a specified effect within a given time frame [41].

Results

Study flow and attrition

Figure 1 illustrates the study participant flow. An analysis of participant drop-out indicated no significant differences in the demographic data or the outcome measurements at T1 between those subjects participating and those dropping out at T2. There were no reported harms or unintended effects of the intervention. Some students reported that they experienced adverse emotional, mental or bodily states during mindfulness practice. However, this was not considered to be unintended effects of the intervention, but rather expected results of becoming more mindful of inner experiences.

Descriptive analyses and randomisation check

There were no significant differences between the intervention and control group on the outcome measures or the demographic variables at T1, except for gender (Table 3). Demographic variables and outcome measures at T1 did not differ by study subject (medicine or psychology) or study location (Oslo or Tromsø). The level of mental distress in our study was high, and 25% of the men and 36% of the women scored above the GHQ12 cut-off score (i.e. ≥4). The gender difference in mental distress was significant ($\chi^2 = 5.58$, $p = .02$). Compared with men, women also scored higher on study stress ($F_{1,287} = 8.08$, $p < .01$) and on the mindfulness facet 'observe' ($F_{1,287} = 4{,}62$, $p < .05$). Table 1 and Table 2 outline all descriptive data for the measurements at T1 and T2 for the intervention and control groups respectively.

Effects of the intervention on the main outcome measures

The MANCOVA analysis revealed a significant overall effect on the main outcome measures of the intervention

Table 1 Outcome measures at T1 and T2 for the intervention and control group

	Intervention n =144 Women n = 118 Men n = 26		Control n =144 Women n = 101 Men n = 43			
	T1	T2	T1	T2	Hedges' g (95% CI)	$F_{1,287}$ Women $F_{1,218}$ Men $F_{1,67}$ (p-value)
GHQ12	**12.4 (6.0)**	**9.2 (4.0)**	**13.0 (6.2)**	**13.2 (6.1)**	**0.65 (.41, .88)**	**44.55 (<.001)**
Women	12.8 (5.9)	9.2 (4.1)	13.9 (6.3)	14.1 (6.1)	0.72 (.45, .99)	47.21 (<.001)
Men	10.8 (6.1)	9.3 (3.4)	11.0 (5.6)	11.1 (5.6)	0.33 (−.16, .82)	2.28 (.136)
Burnout	**32.3 (12.4)**	**32.9 (12.1)**	**32.0 (11.8)**	**34.4 (11.2)**	**0.15 (−.08, .38)**	**1.63 (.204)**
Women	32.2 (12.9)	32.7 (11.9)	32.5 (12.1)	35.3 (11.9)	0.19 (−.08, .46)	3.69 (.056)
Men	32.5 (14.0)	33.9 (13.1)	30.7 (11.0)	32.4 (9.3)	0.02 (−.47, .51)	0.08 (.779)
PMSS	**18.9 (6.9)**	**18.4 (6.8)**	**19.5 (7.0)**	**20.3 (7.4)**	**0.17 (−.07, .40)**	**5.38 (.021)[a]**
Women	19.1 (6.8)	18.3 (6.5)	20.6 (7.3)	21.6 (7.9)	0.25 (.02, .52)	9.58 (.002)
Men	17.6 (7.4)	18.9 (7.9)	16.9 (5.6)	17.1 (5.2)	0.17 (−.32, .66)	1.09 (.300)
SWB	**6.3 (1.8)**	**6.8 (1.4)**	**6.4 (1.8)**	**6.1 (1.8)**	**0.40 (.27, .63)**	**16.16 (<.001)**
Women	6.3 (1.7)	6.8 (1.4)	6.2 (1.8)	5.8 (1.9)	0.61 (.34, .88)	32.15 (<.001)
Men	6.4 (2.1)	6.3 (1.5)	6.8 (1.7)	6.9 (1.5)	0.19 (−.30, .68)	1.88 (.175)

Note. Means (SD), g between group Hedges effect sizes and p-values from univariate tests across gender. *CI* Confidence Interval based on pooled post-intervention SD. Bold characters reflect data for the whole sample.
[a]Did not reach significance using a Bonferroni-corrected alpha-level of 0.0125.

Table 2 Outcome on 5 mindfulness measures at T1 and T2 for the intervention and control group

	Intervention n =144 Women n = 118 Men n = 26		Control n =144 Women n = 101 Men n = 43			
	T1	T2	T1	T2	Hedges'g (95% CI)	$F_{1,287}$ Women $F_{1,218}$ Men $F_{1,67}$ (p-value)
Non Reacting	**20.5 (3.8)**	**21.9 (3.6)**	**20.4 (3.9)**	**20.7 (4.0)**	**0.33 (.10, .56)**	**10.70 (<.001)**
Women	20.4 (3.7)	21.9 (3.7)	20.2 (4.0)	20.7 (4.2)	0.27 (.00, .54)	6.78 (.010)
Men	21.2 (4.1)	22.2 (2.8)	20.8 (3.7)	20.8 (3.4)	0.32 (–.17, .81)	3.22 (.077)
Non Judging	**25.4 (5.6)**	**26.4 (5.2)**	**25.9 (5.4)**	**26.4 (5.2)**	**0.17 (–.06, .40)**	**2.98 (.085)**
Women	25.3 (5.9)	26.9 (5.4)	25.3 (5.6)	25.5 (5.5)	0.27 (.00, .54)	7.31 (.007)
Men	25.9 (5.2)	26.5 (4.3)	27.2 (4.7)	28.7 (3.9)	0.21 (–.28, .70)	3.70 (.059)
Act Aware	**23.8 (5.2)**	**24.4 (4.6)**	**24.8 (5.9)**	**24.6 (5.5)**	**0.15 (–.08, .38)**	**1.02 (.314)**
Women	24.0 (5.0)	24.5 (4.62)	24.4 (5.5)	23.8 (5.6)	0.18 (–.09, .45)	3.492 (.063)
Men	23.4 (6.0)	24.0 (4.8)	25.9 (6.0)	26.4 (4.8)	0.02 (–.47, .51)	1.293 (.290)
Describe	**28.6 (5.6)**	**29.6 (5.3)**	**29.3 (5.1)**	**29.9 (5.2)**	**0.06 (–.17, .29)**	**0.13 (.719)**
Women	28.5 (5.7)	29.6 (5.2)	29.2 (5.1)	30.2 (5.7)	0.03 (–.24, .30)	.000 (.987)
Men	29.2 (5.4)	29.5 (5.9)	29.4 (5.3)	29.4 (3.8)	0.07 (–.42, .56)	.052 (.820)
Observe	**26.7 (5.0)**	**27.4 (5.1)**	**26.7 (5.3)**	**26.4 (5.7)**	**0.17 (–.06, .40)**	**4.54 (.034)**[a]
Women	27.0 (5.2)	27.6 (5.2)	27.1 (5.1)	26.8 (5.6)	0.14 (–.13, .41)	2.334 (.128)
Men	25.5 (3.9)	26.5 (4.2)	25.6 (5.7)	25.3 (5.9)	0.25 (–.24, .74)	1.946 (.168)

Note. Means (SD), *g* between group Hedges effect sizes and *p*-values from univariate tests across gender. *CI* Confidence Interval based on pooled post-intervention SD. Bold characters reflect data for the whole sample.
[a]Did not reach significance using a Bonferroni-corrected alpha-level of 0.01.

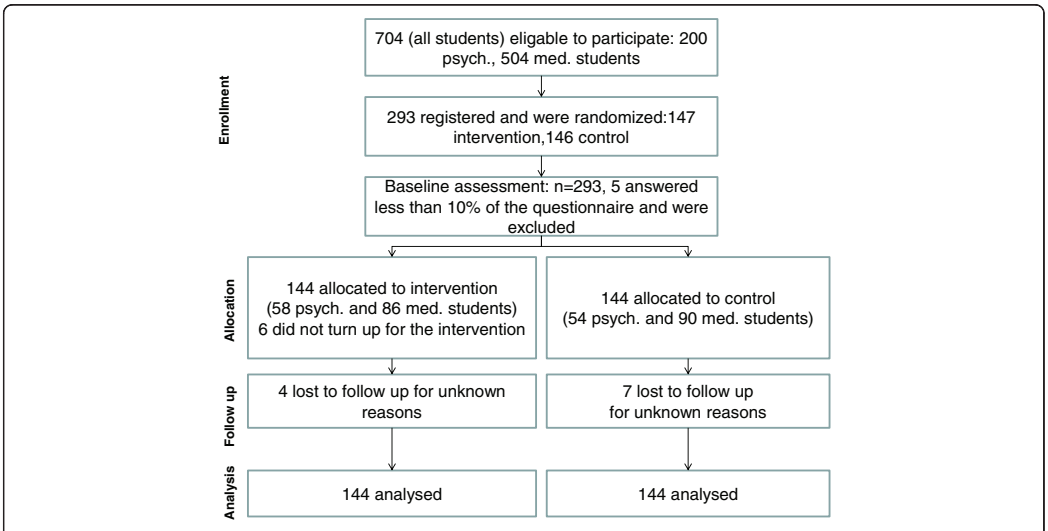

Figure 1 Flowchart describing recruitment and dropout.

Table 3 Socio-demographic characteristics of the intervention and control group at T1

Characteristic	Overall	Intervention	Control	*p*-value
	N = 288	*n* = 144	*n* = 144	
Mean age (SD)	23.8 (5.2)	23.6 (4.7)	24 (5.7)	.58
Women, N (%)	219 (76)	118 (82)	101 (70)	.03
University, N (%)				.63
Oslo	179 (62)	87 (60)	92 (64)	
Tromsø	109 (38)	57 (40)	52 (36)	
Study, N (%)				.72
Medicine	176 (61)	86 (60)	90 (62)	
Psychology	112 (39)	58 (40)	54 (38)	
Civil status, N (%)				.16
Married/cohabiting	86 (30)	37(26)	49 (34)	
Single	202 (70)	107 (74)	95(66)	
No of children, N (%)				.34
0 children	269 (93)	137 (95)	132(92)	
1-5 children	19 (7)	7 (5)	12 (8)	

compared with the control group ($F_{1,\ 287} = 12.06$, $p < .001$). Follow-up univariate ANCOVA analysis showed a significant effect of the intervention on mental distress and well-being. The intervention did not significantly reduce student stress or student burnout (Table 1). The number of students scoring below a cut-off score of ≥4 on GHQ12 at T2 was 128 in the intervention and 84 in the control group. We calculated an absolute risk difference of 0.31 and a NNT = 1/0.31 = 4.

When gender was included as a factor in the MANCOVA analyses of the main outcomes, the effect of the intervention remained significant ($F_{1,\ 287} = 6.64$, $p < .001$) and, in addition, the interaction effect of group × gender was significant ($F_{1,287} = 5.34$, $p < .001$). Follow-up ANCOVA analyses indicated that the intervention had a significant effect for women on mental distress, subjective well-being and student stress, but not for men (Table 1). The direction of the effects is illustrated in Figure 2. Women also showed a reduction in burnout in the expected direction ($F_{1,287} = 3.69$, $p = .056$).

Effect of the intervention on the mindfulness facets

A MANCOVA analysis with the five mindfulness facets at T2 as dependent variables and their corresponding T1 measurements as covariates showed an overall significant effect in favour of the intervention group ($F_{1,287} = 3.10$, $p < .01$). Using a Bonferroni-corrected alpha-level of .01, follow-up analyses showed that the effect was only significant on the non-reactive mindfulness facet scores (Table 2). Adding gender as a between-group factor did not reveal any interaction between group and gender, but separate analyses for gender indicated that the effect for female students was also significant on the mindfulness facet 'non-judging' (Table 2).

Effects of study, university location, course instructor, mindfulness practice and attendance on the outcome measures

Multilevel mixed linear regression analyses indicated that the intervention effects on mental distress and well-being did not vary by university location, course instructors, student class or the type of study.

Men and women attended the intervention group and practised mindfulness to the same degree (ANOVA, $F_{1,143} = 1.26$, $p = .26$ for attendance and, $F_{1,143} = 0.74$, $p = .39$ for practice). The average attendance rate was 5.3 (SD 1.9) out of seven sessions. The students in the intervention group reported undertaking formal practice 1.5 times a week on average, with an average duration of 13 minutes per session. The degree of attendance and sum of the duration of the home practice of mindfulness were significant moderators of the treatment effect in terms of mental distress at T2 when controlling for mental distress at T1 and gender. More exercise ($\beta = .24$, $p < .05$) and more attendance ($\beta = .25$, $p < .01$) were associated with increased intervention effect. The degree of exercise also predicted levels of the non-reactive mindfulness facet ($\beta = .33$, $p < .001$). The other outcome measures were not significantly moderated by attendance and mindfulness practice.

Discussion and conclusions

As hypothesised, the seven-week course in mindfulness training reduced mental distress and improved student well-being independent of the student classes (medicine or psychology), university locations (Oslo and Tromsø), and course instructors. The intervention had no statistically significant effect on student burnout. Only female students showed a significant intervention effect on mental distress, study stress and well-being. A higher level of class attendance and mindfulness practice at home increased the effect of the intervention, particularly for mental distress. The intervention increased the ability of female students to be mindful with acceptance and not to react automatically to internal and external stimuli.

Our findings concur with other studies of students which have reported similar increases in positive states of mind as a result of MBSR interventions [16,19]. Reductions in mental distress and improved well-being in medical students have been observed previously in randomised mindfulness intervention studies [15,17]. However, the current study is the first randomised controlled trial to show that a mindfulness intervention can reduce mental distress and study stress and increase subjective well-being in medical *and* psychology stu-

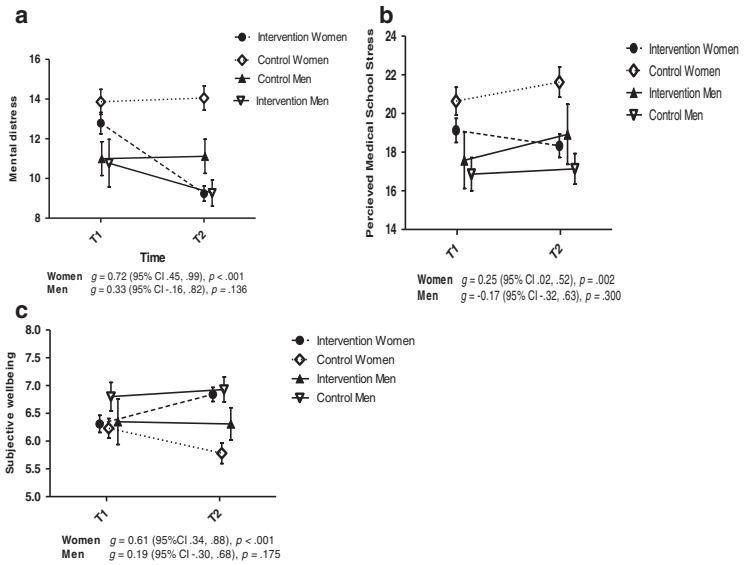

Figure 2 Gender effects of MBSR intervention (means, SD) on mental distress (Figure 2a), perceived medical school stress (Figure 2b) and subjective wellbeing (Figure 2c) including means and SD.

dents. It is also the first study to demonstrate that an MBSR intervention for students may work within a non-USA cultural setting. Further, our study is the first randomised controlled study to report on differential gender effects of participating in an MBSR intervention.

The effect of the course on mental distress was moderate and is in keeping with findings from other controlled MBSR student intervention studies. Jain et al. (2007), for example, noted large effect sizes on mental distress, rumination and positive states of mind following a four-week MBSR course for medical and nursing students [17], while Shapiro et al. (1998) noted moderate effect sizes on mental distress, anxiety and depression following a seven-week MBSR course for medical students [15]. Our study reported a NNT value of 4 which is a measure of the practical relevance of our intervention on mental distress. This NNT indicates that in order to move one student from above to below the cut-off score for mental distress, four students would need to receive the intervention.

To our knowledge, only two controlled studies have previously investigated the impact of gender on the effect of the MBSR programme [24,42]. Both included adult populations and reported equal gender effects. In a review of gender differences in the effect of MBSR treatments for substance abuse disorders, two papers based on one controlled trial found no gender-specific effects, and two quasi-experimental studies indicated a larger benefit among women [43]. Our study showed a gender difference in the effect of the MBSR intervention in favour of women. Although men did experience a small effect on mental distress in our study, this effect was not statistically significant, possibly due to the fact that there were significantly fewer men in the intervention group than the control group.

At T1, women reported higher study stress and mental distress, a finding which has been previously reported [22,23]. Such gender differences in reporting distress may be related to biological processes related to how stress and emotions are *experienced* [44] as well as gender-specific socialisation processes associated with how stress and emotions are *expressed* [45,46]. The seven weeks of mindfulness practice may have helped male students to become more *aware* of their distress, but may have assisted female students with *handling* their distress better. These findings suggest that men may need more extensive – or different forms – of mindfulness training in order to obtain satisfactory benefits. However, our finding could also be specific to students and due perhaps to differences in maturity specific to this age range. Future qualitative interviews with the male students who participated in the study may shed further light on this issue.

Interestingly, women at T1 scored higher on the 'observe' facet of mindfulness. For students who do not practise mindfulness, the ability to observe is inversely correlated with mental health measures [37]. By learning mindfulness, student mental health can be enhanced

through an improved ability to observe *with* an acceptance that is non-judging and non-reacting [47]. Our findings are similar to these earlier results given that the female students reported both enhanced mental health *and* scored significantly higher on the 'non-reacting' and 'non-judging' facets of mindfulness after the intervention. These findings are further supported by research showing the importance of these two facets of mindfulness on the effect of the intervention [48].

Course attendance and the home practice of mindfulness moderated the intervention effects on mental distress but did not affect subjective well-being. Several studies however have reported inconsistent results regarding the relationship between student compliance (attendance and practice) and outcome [14,49] ranging from no correlation [17] to a positive correlation [15].

Recently, several mediation analysis studies have supported a causal relationship between increased mindfulness and positive health outcomes [24,38,50] and this finding will be tested in a two-year follow-up of our study. However, we have found only small effect sizes for mindfulness, and the level of mindfulness measured at T2 is considerably lower than those reported in studies of experienced meditators [48]. This may be due to the low levels of formal home practice reported by the students. Whether additional practice could result in increased levels of mindfulness will be evaluated in our follow-up studies. We still do not fully know how mindfulness practice works or the specific individual characteristics that help to promote the effects of MBSR. Different people may, for instance, need different amounts and types of practice. That only practice rather than attendance per se was a predictor of variation in the 'non-reacting' facet of mindfulness may indicate that the degree to which one practises mindfulness is a plausible key to understanding the effects of the intervention. The reason why attendance and practice did not predict changes in well-being is difficult to explain and future studies are needed to explore this issue in greater depth.

The research strength of this study was enhanced in a number of ways, including the use of a computer-randomised controlled design, concealment of allocation, an electronic assessment of the outcomes which remained free of the influence of the study evaluators, and the low level of sample attrition. Also, the fact that the effects were found irrespective of the student classes, study sites, and course instructors makes it possible to assume that the effects were due to the mindfulness intervention itself. A broader intervention strategy may have enabled more students to participate.

The limitations of the study include a possible selection bias during recruitment which may have affected the results. As only 40% of the eligible students volunteered to participate, those students who were recruited might have been more motivated to take part and possibly more primed to focus on psychological and personal issues. In addition, because the active ingredients of the intervention are "transportable" and participants from the intervention group and the control group interacted during and after the intervention period, contamination may have occurred, which may have influenced the magnitude of the effect sizes. Moreover, because the study randomisation was not stratified for gender, only 26 men received the intervention. Necessarily, this resulted in insufficient statistical strength and inconclusive interpretations regarding the impacts of the intervention on male students. The study did also not include a comparable control intervention in which the same amount of attention from instructors and regular participation was provided within a supportive group of fellow students. Thus we are unable to specify which particular elements of the intervention may have been more strongly associated with the resultant outcomes. Participants were also not asked to keep daily logs of their mindfulness exercises, and it's possible that such records may have helped to shed light upon the impact of the exercise on outcomes. The suboptimal property of the non-reactivity facet of mindfulness has also limited our conclusions related to the mindfulness effect of the intervention. Finally, adherence to the MBSR manual was not systematically evaluated in terms of, for example, the use of video or audio recordings during the intervention sessions.

In conclusion, the present study shows that teaching medical and psychology students to relate mindfully to current internal and external stimuli can decrease mental distress and increase well-being. There is a need for more research on mindfulness-based interventions that includes gender as a variable. The degree to which this MBSR intervention will influence mental distress and subjective well-being in the students' later years of studies and in their professional career is a research question that will be addressed in our follow-up studies.

Competing interest

The authors declare that they have no competing interests.

Authors' contributions

MdV, AB and RT defined the research theme and designed the study. IS, JR and TS helped in the design of the study. MdV and IS were responsible for recruitment, intervention delivery and the acquisition of data, and they analysed and interpreted the data and drafted the manuscript. AB, RT, JR and TS helped to interpret the data and revise the manuscript critically for important content. OF helped with the statistical analyses and the interpretation of the data and revised the manuscript critically. All authors read and approved the final manuscript.

Acknowledgements

We would like to thank Oluf Jensen at the Norwegian Knowledge Centre for the Health Services for putting the questionnaire online and for securing the randomisation and allocation process. We also wish to thank the Norwegian Medical Association, Helse Nord, and the Norwegian Knowledge Centre for the Health Services for funding this study.

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Received: 23 October 2012 Accepted: 31 July 2013
Published: 13 August 2013

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doi:10.1186/1472-6920-13-107
Cite this article as: de Vibe *et al.*: Mindfulness training for stress management: a randomised controlled study of medical and psychology students. *BMC Medical Education* 2013 **13**:107.

III

Mindfulness
DOI 10.1007/s12671-013-0258-y

ORIGINAL PAPER

Does Personality Moderate the Effects of Mindfulness Training for Medical and Psychology Students?

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Abstract The majority of mindfulness research to date has reported only on the group-level effects of interventions. Therefore, there is a need to better understand who is most likely to benefit from mindfulness interventions. This study reports on moderation analyses from a two-centre randomised controlled trial of mindfulness-based stress reduction (MBSR) among 288 medical and psychology students. The study investigated whether baseline personality factors (neuroticism, conscientiousness and extroversion) and baseline mindfulness moderated effects on mental distress, study stress and subjective well-being measured after the intervention. An increased effect of the intervention on mental distress and subjective well-being was found in students with higher scores on neuroticism. Students with higher scores on conscientiousness showed an increased effect of mindfulness training on study stress. The training protected students against an increase in mental distress and study stress and a decrease in subjective well-being that was seen in the control group. Baseline mindfulness and extroversion did not moderate the effects of the intervention on the outcomes. The majority of the 288 medical and psychology students in the study sample were female. Female participants scored significantly higher on neuroticism and conscientiousness, and they may therefore be an important target group for mindfulness interventions among students.

Keywords Mindfulness · MBSR · Personality · Moderation · RCT · Students

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Introduction

Research evidence has increasingly demonstrated the positive effects of mindfulness-based interventions on a range of outcomes in clinical and non-clinical populations on a group level (de Vibe et al. 2012). However, more insight is needed about who would most likely benefit from such interventions. A classic question within intervention research asks: 'What works for whom?' Mindfulness researchers, too, require a better understanding of the moderators of outcomes. Insights of this kind could also help to guide adaptations of mindfulness programmes to meet the needs of different populations (Kazdin 2008).

There are many possible factors that could moderate the effects of mindfulness training. Personality traits are among

Published online: 27 October 2013

the likely candidates to investigate as mindfulness has been found to correlate with Eysenck's (1990) 'Big Five' personality traits of neuroticism, extroversion, openness to experience, agreeableness and conscientiousness (Giluk 2009). However, research results have been sparse, and there is a need for more studies to clarify how mindfulness relates to personality traits (Giluk 2009). This article will look at the 'Big Three' personality dimensions of neuroticism, conscientiousness and extroversion (Eysenck 1994) and whether these characteristics moderate the effects of mindfulness training.

Neuroticism has previously been found to be an important predictor of anxiety and depressive symptoms and higher levels of neuroticism (characterised by anxiety, self-consciousness, moodiness and insecurity), predicted a better outcome following a brief mindfulness intervention in a non-controlled study of 133 adults (Lane et al. 2007). Higher baseline levels of neuroticism were associated with greater effects on stress, mood disturbance and state anxiety at 4, 8 and 12 weeks of follow-up, respectively. Individuals with pronounced neuroticism may, however, display low levels of adherence and may find it difficult to practice mindfulness (Delmonte 1988). The difficulty of differentiating between covariate effects and regression to the mean in uncontrolled studies may therefore have affected the validity of the observations made.

Conscientiousness and extroversion may also moderate the effect of mindfulness interventions, although, to our knowledge, no studies of such effects have been reported in the literature. Conscientiousness (characterised by being responsible, rule abiding and controlling) has been found to predict student stress in medical students (Tyssen et al. 2007). However, in a meta-analysis of seven cross-sectional studies, a positive correlation between conscientiousness and mindfulness was reported (Giluk 2009). In addition, a pilot study in a non-clinical student population has shown that mindfulness training may help to reduce obsessive–compulsive symptoms (Hanstede et al. 2008). However, the relevance of this latter finding in relation to conscientiousness is uncertain. Extroversion (characterised by talkativeness, sociability and assertiveness) has been linked to subjective well-being and positive emotionality (Diener 2000) and to mindfulness (Baer et al. 2006; Brown et al. 2007), yet a meta-analysis of 11 studies has shown only a moderate positive correlation between extroversion and mindfulness (Giluk 2009).

Mindfulness has also been considered a personal characteristic, and it has been shown to be inversely related to neuroticism (Baer et al. 2006), but whether baseline levels of mindfulness moderate the effects of mindfulness training remains unclear. A small study of a mindfulness-based stress reduction (MBSR) intervention, using a sample of 30 undergraduate students, found that participants with higher levels of baseline mindfulness showed a larger increase in mindfulness, subjective well-being, empathy and hope and larger declines in perceived stress up to 1 year after the intervention, compared to the wait list control group (Shapiro et al. 2011). In an uncontrolled study where a small community sample received brief mindfulness training, no moderating effect of mindfulness on mental distress was found (Sass et al. 2013).

Previous studies, which may therefore be argued, have indicated that baseline levels of neuroticism and mindfulness may possibly moderate the effect of MBSR training on mental health outcomes, while there is only correlational evidence on the relationship between mindfulness and the personality traits of extroversion and conscientiousness. Overall, however, the research in this field remains sparse. In addition several studies were conducted without control groups and had low statistical power. The purpose of this study was to avoid these previous methodological shortcomings when examining potential moderators of the effects of mindfulness training on mental distress, student stress and well-being in medical and psychology students. Previously, we have reported that mindfulness training had a moderately large effect on mental distress and subjective well-being and a small effect on study stress among female medical and psychology students (de Vibe et al. 2013). This article presents new data from the same trial in order to investigate which students benefited the most from the mindfulness intervention.

Our hypotheses were that higher levels of neuroticism and mindfulness would predict a larger effect of the intervention on mental distress, student stress and subjective well-being. The moderation analyses for conscientiousness and extroversion are exploratory and hypothesis-generating in nature.

Method

A moderator of an intervention is a pretreatment or baseline variable that identifies subgroups within the population with a different effect of the intervention (Kraemer et al. 2006).

Participants

The population in this trial was 288 1st- and 2nd-year medical and psychology students. Two hundred eighty-eight students were randomised, 144 to receive a 7-week MBSR programme and 144 students to the control group. They received no intervention and continued their studies as before. Data were collected before and after the intervention. Seven hundred four students were invited to participate, and 69 male and 219 female students took part. The mean age was 24 years, 70 % were single, and 7 % had children. Figure 1 shows the flow chart from the study. Details of the randomisation procedure and study recruitment are provided in the study of de Vibe (2013).

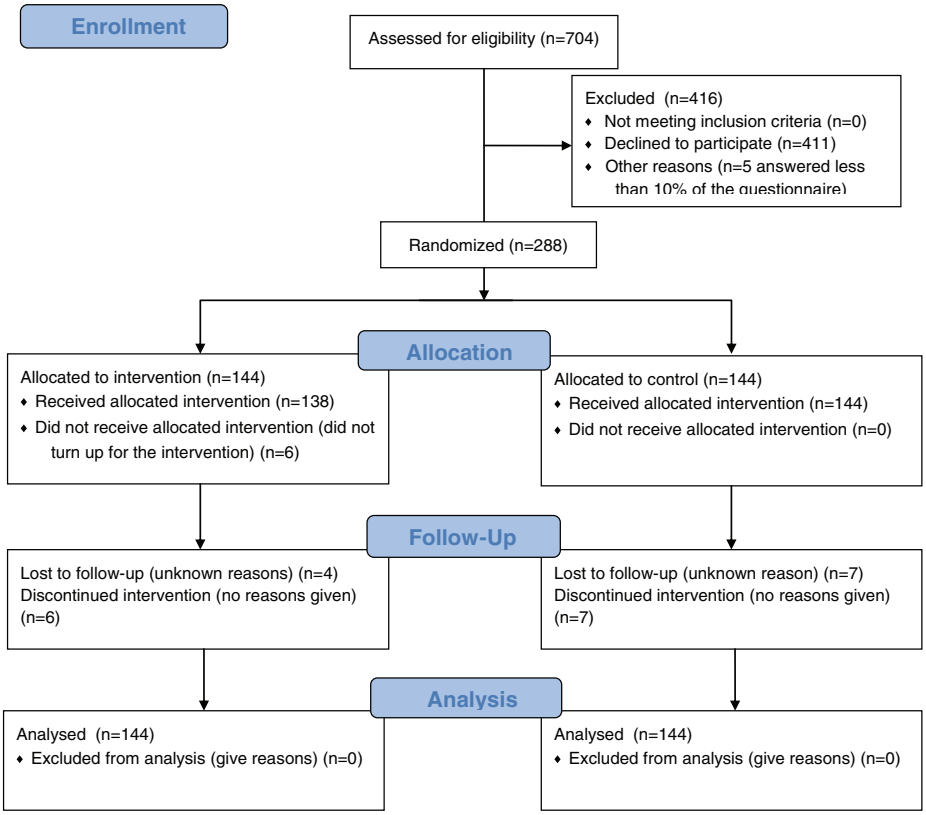

Fig. 1 Study flow chart

Measures

Mental Distress

The General Health Questionnaire (GHQ) (Goldberg and Williams 1988) was used to assess levels of mental distress experienced during the previous 2 weeks. It consists of 12 items, and responses are scored as '0' (much less than usual), '1' (less than usual), '2' (same as usual) or '3' (more than usual). The maximum score can range from 0 to 36 (high distress). The Norwegian version has shown good psychometric properties among 1st-year university students (Nerdrum et al. 2006). Internal consistency in our sample was Cronbach's alpha=0.90.

Student Stress

The 13-item Perceived Medical School Stress (PMSS) scale (Vitaliano et al. 1984) was used to measure student stress. The Norwegian version has been validated in samples and cohorts of medical students (Bramness et al. 1991; Tyssen et al. 2001, 2007). In our study the word 'medical' was removed from the terms 'medical school' and 'medical training' to make all items relevant for both medical and psychology students. The PMSS uses a Likert scale ranging from 0 (strongly agree) to '4' (strongly disagree). The total score range is from 0 to '52' (high stress) and Cronbach's alpha was 0.79 for the whole sample (0.78 for medical students and 0.81 for psychology students).

Subjective Well-being

Subjective well-being (SWB) was measured using a Norwegian four-item scale (Moum et al. 1990) that assessed cognitive satisfaction, positive affect and negative affect. The number of response categories varied from 5 to 7, and all items were therefore transformed to a 0–10 scale. The mean sum of the four items was used with a range from 0 to 10 (high

SWB). The Cronbach's alpha was 0.81. SWB has been validated both in Norwegian student and adult populations and has been shown to correlate strongly with Diener's 'Satisfaction with Life Scale' (Røysamb et al. 2002).

Mindfulness

The Five Facet Mindfulness Questionnaire (FFMQ) sum score was used to measure mindfulness. It has 39 items, and a Norwegian version has been validated in three samples of 792 1st-year Norwegian psychology students (Dundas et al. 2013). Item scores range from 1 (never or very seldom true) to '5' (very often or always true), and the total possible score range is from 39 to 195 (high mindfulness). The Cronbach's alpha of 0.79 reported for this study sample was similar to those reported in previous studies (Baer et al. 2006). The validity of the FFMQ is supported by studies showing positive correlations with meditation experience, openness to experience, emotional intelligence and self-compassion and negative correlations with psychological symptoms, neuroticism, thought suppression and difficulties with emotional regulation (Baer et al. 2006).

Personality

Personality traits were measured using the Norwegian 27-item Basic Character Inventory (BCI) (Torgersen 1980; Alnæs and Torgersen 1990) covering three dimensions, each measured using nine dichotomously scored items (the dimensional scores range from 0 to 9). The three dimensions were neuroticism (Cronbach's alpha=0.75), conscientiousness (Cronbach's alpha=0.68) and extroversion (Cronbach's alpha=0.77). These personality traits have been validated previously in longitudinal studies of Norwegian medical students and young doctors (Kjeldstadli et al. 2006; Tyssen et al. 2007; Røvik et al. 2007).

Statistical Analysis

Intention-to-treat analyses were used. Missing data (4 %) were imputed using the last observation carried forward—a conservative statistical method when drop-out rates in the intervention and the control group are equal (Lane 2008). Bivariate (zero-order) correlation analyses were used to examine the relationships between the moderators and baseline levels of the outcome measures. Independent t tests were performed to compare the personality factors of the male and female students.

Assuming that there is a gradual change in the effect of the intervention (predictor) depending on the level of the moderator, moderation can be examined by including the product of the predictor and the moderator as an interaction term in a multiple hierarchical regression analysis. To be statistically valid, moderators should be roughly equally distributed across study groups and not too highly correlated with the outcome variables (Baron and Kenny 1986). Multiple hierarchical regression analyses were performed separately for each outcome using unstandardised variables (Echambadi and Hess 2007). Each moderator was tested against all four outcomes. Gender was not stratified in the randomisation process, and men were over-represented in the control group (43 versus 26). Hence, gender was entered together with the baseline value of the outcome variable in the first step of the regression model. In the second step, the treatment (intervention versus control) and the moderator variable was entered. In the final step, the multiplied term of the treatment and the moderator variable was entered, representing the statistical test of moderation. Statistically significant moderators were examined visually by graphing the treatment effect on the outcome variable at different levels of the moderator. The Johnson–Neyman (J-N) technique was used to identify at what level of the moderator the moderation became statistically significant (Johnson and Neyman 1936).

Results

Descriptive statistics and correlation coefficients between all the baseline variables are reported in Table 1. In addition, all students were asked how often they practised mindfulness, and there was no difference between the groups. The correlation analyses showed that neuroticism was positively correlated with GHQ and PMSS and negatively correlated with SWB. Neuroticism showed an inverse correlation with FFMQ and extroversion and a positive correlation with conscientiousness. Women scored significantly higher than men on neuroticism (5.3 versus 3.6, $t_{286}=5.37$, $p<0.001$, $d=0.7$) and conscientiousness (4.2 versus 3.4, $t_{286}=2.61$, $p=0.01$, $d=0.4$), but not on extroversion (5.8 versus 5.2).

All significant regression coefficients are shown in Table 2, and the interaction effects are illustrated in Figs. 2, 3 and 4. Students with a higher baseline level of neuroticism reported a larger intervention effect on GHQ ($R^2_{\text{change}}=0.01$, $F_{1,\ 282}=3.85$, $p=0.05$) and on SWB ($R^2_{\text{change}}=0.01$, $F_{1,\ 282}=6.28$, $p=0.01$) than students with a lower baseline level of neuroticism. The result for PMSS was not significant. In the treatment group, MBSR was found to lower mental distress (GHQ) and improve well-being (SWB) as baseline neuroticism increased, compared with the control group in which GHQ and SWB worsened with increasing neuroticism (Figs. 2 and 3). The J-N technique indicated a significant group difference on GHQ for students scoring >1.1 on the neuroticism scale (90 % of the students). For SWB, the interaction became significant for students scoring >3.2 on neuroticism (67 % of the students).

Table 1 Correlations and descriptive statistics of predictors, moderators and baseline values of outcome measures (n =288)

Variables	1	2	3	4	5	6	7	8	9
1. Group[a]	–								
2. GHQ	−0.05	–							
3. PMSS	−0.05	.46**	–						
4. SWB	−0.02	−0.73**	−0.53**	–					
5. Gender (0, ♀; 1, ♂)	−0.14*	−0.17**	−0.17**	0.09	–				
6. Neuroticism	0.07	0.46**	0.52**	−0.55**	−0.30**	–			
7. Conscientiousness	−0.11	0.11	0.21**	−0.09	−0.15*	0.29**	–		
8. Extroversion	−0.03	−0.07	−0.15*	0.17**	−0.09	−0.21**	−0.18**	–	
9. FFMQ	−0.06	−0.43**	−0.39**	0.54**	0.05	−0.55**	−0.06	0.25**	–
M	0.50	12.72	19.18	6.36	0.24	4.89	4.01	5.64	126.06
SD	0.50	6.09	6.94	1.75	0.43	2.46	2.27	2.47	15.44

GHQ General Health Questionnaire, *PMSS* Perceived Medical School Stress, *SWB* subjective well-being, *FFMQ* Five Facet Mindfulness Questionnaire

*p <0.05; **p <0.01

[a] Group: 0=control, 1=MBSR

Increasing levels of baseline conscientiousness indicated an increased effect of the MBSR intervention on PMSS (R^2_{change}=0.01, $F_{1,\ 282}$=6.28, p =0.01), compared to the control group which showed an opposite effect (Fig. 4). Conscientiousness did not moderate the effect of the intervention on SWB and GHQ. Applying the J-N technique yielded a significant conditional effect of conscientiousness on PMSS for students scoring >3.6 on the conscientiousness scale (52 % of the students). Extroversion and mindfulness were not significant as moderators.

Discussion

The moderation analyses in this study revealed that students who scored high on neuroticism benefitted more from the MBSR intervention and had lower levels of mental distress and increased subjective well-being post-intervention, compared to those in the control group. Graphing of the interaction effects indicates that the intervention may have protected students in the intervention group against the impact of increased mental distress and decreased subjective well-

Table 2 Hierarchical multiple regression analysis of significant interactions

	GHQ		SWB		PMSS	
	ΔR^2	β	ΔR^2	β	ΔR^2	β
Step 1	0.11***		0.29***		0.43***	
Control variables[a]						
Step 2	0.12***		0.05***		0.02*	
Group		−0.36***		0.22***		−0.11*
Neuroticism		0.02		−0.13*		
Conscientiousness						−0.07
Step 3	0.01^		0.02**		0.01*	
Group × neuroticism		−0.26*		0.34**		
Group × conscientiousness						−0.24*
Total R^2	0.32***		0.36***		0.45***	

Predicting GHQ and SWB from group, neuroticism and group × neuroticism and predicting PMSS from group, conscientiousness and group × conscientiousness; N=288; group: 0=control, 1=MBSR; gender: 0=female, 1=male

GHQ General Health Questionnaire, *SWB* subjective well-being, *PMSS* Perceived Medical School Stress

^p =0.05; *p <0.05; **p <0.01; ***p <0.001

[a] Control variables are gender and baseline value of the outcome variable

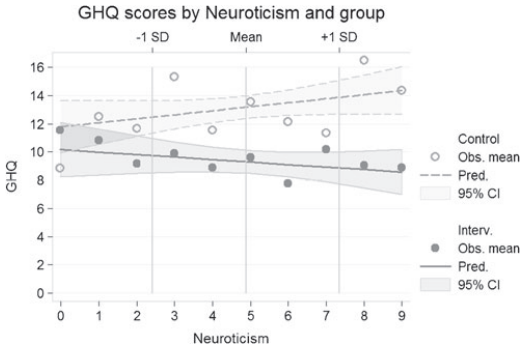

Fig. 2 Post-intervention scores for the General Health Questionnaire (*GHQ*) by group and level of neuroticism. Neuroticism scores were unstandardised and adjusted for gender and baseline GHQ. *Obs. mean* observed mean, *Interv.* intervention, *SD* standard deviation, *CI* confidence interval

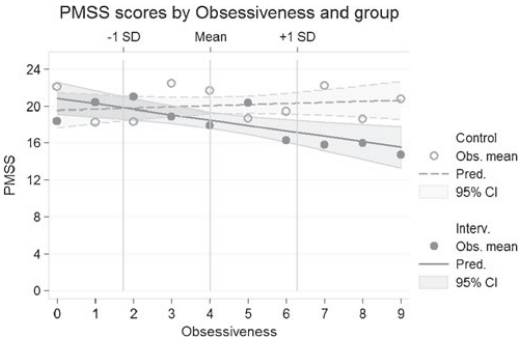

Fig. 4 Post-intervention scores for Perceived Medical School Stress (*PMSS*) by group and level of conscientiousness. Conscientiousness scores were unstandardised and adjusted for gender and baseline PMSS. *Obs. mean* observed mean, *Interv.* intervention, *SD* standard deviation, *CI* confidence interval

being associated with increasing levels of neuroticism that was observed in the control group. The effect of the intervention on reducing student stress was particularly evident in students who scored higher on conscientiousness. Baseline levels of extroversion and mindfulness did not moderate the effect of the intervention.

Neuroticism is an expression of emotional vulnerability and has been clearly linked to anxiety and depression in a recent meta-analysis of cross-sectional studies with control groups (Kotov et al. 2010). Neuroticism has been found to predict future student stress in a 6-year follow-up study of medical students (Tyssen et al. 2007), and a 15-year follow-up of medical doctors found neuroticism to be predictive of a three- to fourfold increase in the risk of severe depressive symptoms (Grotmol et al. 2013). Studies with psychology students have reported similar findings (Fetterman et al. 2010), in addition to an inverse relationship between

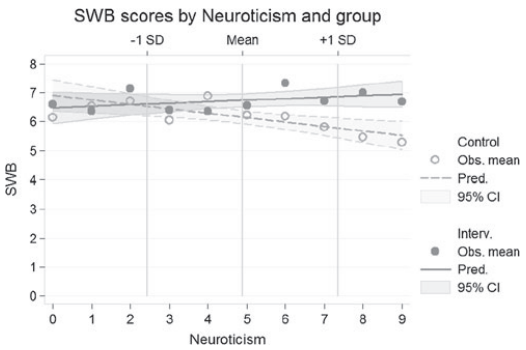

Fig. 3 Post-intervention scores for subjective well-being (*SWB*) by group and level of neuroticism. Neuroticism scores were unstandardised and adjusted for gender and baseline SWB. *Obs. mean* observed mean, *Interv.* intervention, *SD* standard deviation, *CI* confidence interval

neuroticism and mindfulness (Baer et al. 2006). This latter association has also been reported in a meta-analysis of 29 studies with adult populations (Giluk 2009). Similarly, our study showed a strong correlation in the expected direction between baseline values of neuroticism, mental distress, study stress, subjective well-being and mindfulness.

Changes in emotional processing may be a key to understand the protective benefits of mindfulness training for students with higher levels of neuroticism. Neuroticism may be conceptualised in terms of negative emotional reactivity processes (Feltman et al. 2009), and one may argue that individuals with higher emotional reactivity would benefit more from improving their emotional regulation skills to cope better with their emotional reactivity to stress (Connor-Smith and Flachsbart 2007). It is therefore promising that the J-N technique showed that the moderating effect of the MBSR intervention started at low levels of neuroticism and thus benefited the majority of the students. Emotional awareness, acceptance and letting go of negative thoughts—all related to mindfulness practice—are adaptive emotion regulatory strategies (Cordon et al. 2009). That mindfulness training is especially beneficial for students with high stress reactivity lends support to the notion that mindfulness training is an effective mechanism for the improvement of emotion regulation skills.

This is further supported by a study of undergraduate students which showed that increased levels of mindfulness reduced the relationship between neuroticism and the traits of anger and depression (Feltman et al. 2009). Mindfulness, as the authors showed, is not just an inverse representation of neuroticism but is a different psychological characteristic, and both variables predicted anger and depression when simultaneously controlled. The authors proposed that mindfulness training may be particularly beneficial for

distress-prone individuals, and this claim is supported by our findings. Our gender analyses found that only female students benefited significantly from the intervention (de Vibe et al. 2013), and female students scored significantly higher on neuroticism and mental distress than male students. The level of neuroticism in women (both medical and psychology students) was also significantly higher ($t=5.35$, $p<0.0001$) compared to a sample of 140 female Norwegian medical students in a 1993 study (Tyssen et al. 2007). No difference was found in the scores of male students. These findings further highlight the importance of targeting female students for stress management interventions.

The personality characteristic of conscientiousness predicted a differential effect of the intervention on study stress. The MBSR course had an increased effect on students with higher conscientiousness scores (half of the students in our sample). These students may have been more conscientious in terms of their treatment adherence and may therefore have benefited more from the intervention, although evidence for this was not found when comparing attendance rates and reported home practice. Another possibility is that the students who scored higher on conscientiousness may have responded positively to the acceptance and letting go attitude in their mindfulness training. The training may have offered them an alternative to their usual controlling way of relating to the world and to themselves. Over time, such training may influence this personality trait. Initial support for this claim can be found in a study comparing conscientiousness levels in 35 experienced mindfulness practitioners and 35 matched controls (van den Hurk et al. 2011). They found significantly lower scores on conscientiousness among the experienced mindfulness group. In line with this, an intervention study with practising doctors found that 1 year of mindfulness training lowered their level of conscientiousness (Krasner et al. 2009). In our study, the increased scores on study stress at post-intervention among the students in the control group with higher scores on conscientiousness suggest that these students may be more vulnerable to study stress and could thus benefit particularly from this type of intervention. Similar findings were shown in a study of perfectionism among medical students (Enns et al. 2001), which found that achievement striving was significantly correlated with conscientiousness and predictive of dissatisfaction with academic performance 6 months later. The female students in our study scored significantly higher than the male students on conscientiousness. Compared with the scores of female medical students in 1993 (Tyssen et al. 2007), the level of conscientiousness both for female medical and psychology students in our sample was significantly higher ($t=3.80$, $p<0.001$), while no significant differences were noted for male students. This underlines the possible importance of offering mindfulness interventions to people who score high on conscientiousness.

The study intervention protected against the increased mental distress, study stress and lower subjective well-being that was seen in the control group at the post-intervention measurement (which occurred close to the end of term exams). These effects were more pronounced for those who scored higher on neuroticism and conscientiousness, and most of whom were female students. This may indicate that the female students reacted differentially to stress, a suggestion supported by a study showing that healthy men and women engage different neural networks when exposed to moderate psychological stress (Wang et al. 2007). High levels of neuroticism and conscientiousness may also contribute to increased stress reactivity. In Norway, the required entrance grades for medicine and psychology are now very high, and this type of mindfulness intervention may therefore be particularly pertinent to the increasing percentage of women studying these courses.

Contrary to our hypothesis, baseline levels of mindfulness did not moderate the intervention effect. However, a previous study (Shapiro et al. 2011) proposed that people with higher levels of mindfulness may find the mindfulness exercises less demanding to perform, thus leading to greater perceived mental health gains over time. Whether 2 and 4-year follow-up data from this mindfulness trial will confirm this remains to be seen.

The strengths of our study included the relatively large sample size taken from different student classes, universities and curricula. The outcome assessors were blinded to the identity of the participants, and different course instructors were used. However, several limitations were evident: first, because the randomisation was not stratified by gender, only 26 men received the intervention. This made separate gender analyses difficult. Secondly, the use of four possible moderators for each outcome may have increased the risk of false-positive findings. Thirdly, no effort was made to restrict or control possible communication between participants in the intervention and control group. As many of the participants had come from the same student classes and volunteered to participate in a stress management study, communication between them may have affected the results. Finally, only 40 % of the eligible students participated in the study; a lack of information about the remaining students may therefore limit the generalisability of these findings.

In summary, we found that mindfulness training had greater effects on students with higher scores on the personality traits of neuroticism and conscientiousness. The majority of these students were female. There was an increase in mental distress and student stress and lower well-being in the control group after the intervention that was protected against by mindfulness training in the intervention group. These findings will need to be replicated before further, definite, conclusions can be drawn regarding which student groups should be targeted for mindfulness interventions.

Acknowledgments We would like to thank Oluf Jensen at the Norwegian Knowledge Centre for the Health Services for putting the questionnaire online and for securing the randomisation and allocation process. We also wish to thank the Norwegian Medical Association, Helse Nord, and the Norwegian Knowledge Centre for the Health Services for funding this study.

Conflict of Interest The authors declare that they have no competing interests.

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